WORLD HEALTH ORGANIZATION (WHO)

BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL II (BASICS II)

SAFE INJECTION GLOBAL NETWORK (SIGN)

# INJECTION PRACTICES: RAPID ASSESSMENT AND RESPONSE GUIDE

THIS DOCUMENTS IS PART OF A TOOLBOX TO ASSESS AND EVALUATE INJECTION PRACTICES. THE COMPLETE TOOLBOX INCLUDE THE RAPID ASSESSMENT AND RESPONSE GUIDE AND FOUR ADDITIONAL TOOLS (A, B, C, AND D)

This toolbox addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS, Arlington, VA, USA in March 2000. It constitutes a dated draft circulated for comments and suggestions. Although it is made widely available at an early stage, it is not yet intended to be a "how-to" manual for field use. Later versions of this document will be adapted for wider readership level once consensus has been reached on broad concepts and after field testing.

Comments and suggestions should be directed to the Secretariat of the Safe Injection Global Network (SIGN), World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, Geneva 27, Switzerland 1211. Fax +41 22 791 4836. E-mail: sign@who.ch.

| **Intended use and proposed timeline for this document** | |
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| Preparation of a final version after two years of feedback from the field | End of 2002 |

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**TOOL D**

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## ABBREVIATIONS USED IN THIS DOCUMENT

**DHS:** Demographic and Health Survey
**EDM:** Essential Drug and Medicines policy
**EDL:** Essential Drug List
**EPI:** Expanded Programme on Immunization
**GAVI:** Global Alliance for Vaccine and Immunization
**HBV:** Hepatitis B Virus
**HCV:** Hepatitis C Virus
**HIV:** Human Immunodeficiency Virus
**IMCI:** Integrated Management of Childhood Illnesses
**MICS:** Multi-Indicator Cluster Survey
**NGO:** Non Governmental Organization
**SIGN:** Safe Injection Global Network
**WHO:** World Health Organization

## SUMMARY

To prevent injection-associated transmission of bloodborne pathogens, injection frequency should be reduced and safe injection practices should be achieved. At country level, this should be achieved through a multidisciplinary three-element approach that includes (a) behaviour change targeting patients and healthcare workers to reduce injection overuse and achieve safe injection practices, (b) provision of sufficient quantities of adequate injection equipment and infection control supplies, and (c) appropriate sharps waste management. Safe and appropriate use of injection policies may be conducted with greater effectiveness and at lower cost if an initial assessment of injection practices is conducted with the following steps:

1) **Engage all stakeholders** so that the process involves more than just external experts. To engage stakeholders, they should be identified and approached so that they recognize the problem. Potential human, material, and financial resources should be identified, and ongoing mechanisms of information sharing should de developed;

2) **Describe the situation** through application and adaptation of a generic framework; identification of available data as well as planned studies and surveys; and modelling of the expected burden of disease secondary to unsafe injection practices;

3) **Make assessment plans** to determine information needs regarding the consequences of poor practices among recipients; injection practices (injection overuse and proportion of unsafe injections) among providers; and their determinants in the broader system;

4) **Gather credible evidence** using (1) a rapid assessment package to interview injection prescribers, injection providers, and the population and /or (2) an in-depth assessment package made of four additional tools:

    A- A tool to identify the determinants of poor and good injection practices using qualitative methods;

    B- A tool to estimate the frequency of injections and identify injection providers through population surveys and healthcare use indicators;

    C- A tool to assess injection safety through observation of practices;

    D- A tool to assess the association between injections and infections through epidemiological studies.

5) **Justify conclusions** so that a plan of action can de developed on the basis of the results of the assessment**;**

6) **Ensure use** through preparing future use and feedback of process and outcome indicators during the post-intervention evaluation phase**.**

## INTRODUCTION

### RATIONALE

In developing countries, the estimated proportion of injections administered with injection equipment that is re-used without sterilization between patients ranges from 15% to 50%. [1] Surveys conducted in various settings have also indicated that the proportion of prescriptions including at least one injection is high (up to 56%), suggesting that injections are overused to administer medications. [2] As a result of unsafe practices and overuse, injections transmit bloodborne pathogens on a large scale worldwide. [1] Annually, injections cause an estimated 8-16 million cases of hepatitis B virus (HBV) infection, 2.4-4.5 million cases of hepatitis C virus (HCV) infection, and 80,000 to 160,000 cases of Human Immunodeficiency Virus (HIV) infections. [3] These infections lead to a high burden of chronic disease, disability, and death. [4]

To prevent injection-associated transmission of bloodborne pathogens, injection frequency should be reduced and safe injection practices should be achieved. At country level, these goals should be reached through a multidisciplinary three-element approach [5] that includes:

1) Behaviour change targeting patients and healthcare workers to reduce injection overuse and implement safe injection practices;

2) Provision of sufficient quantities of adequate injection equipment and infection control supplies;

3) Appropriate sharps waste management.

This three-element safe and appropriate use of injection policy may be implemented with greater effectiveness and at lower costs if an initial assessment of injection practices and their adverse effects is conducted since:

1) Assessing injection practices identifies relevant local issues so that focused interventions can be conducted;

2) Assessing injection practices and their adverse effects provides baseline information regarding processes (e.g., injection frequency, proportion of unsafe injections) and outcomes (the incidence of injection-associated infections) thus preparing a sound basis for post-intervention evaluation;

3) Collection and feedback of information by an assessment team initiates communication between public health professionals and the various groups that will constitute the future audience of behaviour change strategy, as in an Assessment, Feedback, Incentive, and eXchange (AFIX) process.

Assessment of injection use and injection safety should be **focused** and **action oriented** to aim primarily at directing prevention efforts. Standardization of assessment methods should be sought to compare the situation and the effectiveness of interventions across various settings or at different points in time in the same setting. This rapid assessment and response guide proposes a standardized approach to assess injection practices and propose interventions. When specific aspects of injection practices require further assessment, this guide refers to four additional tools. These four tools may be used to (a) identify the determinants or poor injection practices, to (b) estimate the frequency of injections and

identify injection providers, (c) estimate the frequency of unsafe injection practices, and (d) assess the association between injections and infections.

## WHO SHOULD USE THIS RAPID ASSESSMENT AND RESPONSE GUIDE?

### SENIOR MANAGEMENT PERSONNEL

Senior management personnel responsible for the design, implementation, evaluation, and update of national policy and plans for the safe and appropriate use of injections constitute the primary audience of this guide. Some of the four proposed additional tools require expertise and experience in various aspects of field epidemiology, including public health surveillance, field methods of sampling, and design of analytical risk factor studies (e.g., cross-sectional, cohort, or case-control studies). Senior managers may seek technical input from national and, if necessary, international resources to conduct assessment using these additional tools.

### PERSONS CONDUCTING INJECTION PRACTICES ASSESSMENTS AT A NATIONAL OR REGIONAL LEVEL

Epidemiologists, anthropologists, and other public health workers seeking to conduct comprehensive or specific assessment of injection practices will find tools and template data collection instruments that may be used as a starting point to develop specific survey material.

### INTERNATIONAL EXPERTS

International experts will find this guide useful when being asked to assess or evaluate injection practices in countries where unsafe injection practices are suspected, or targeted by prevention efforts.

### NATIONAL POLICY MAKERS

National policy makers will find this guide useful to understand better the data that is required to develop policies for safe and appropriate use of injections.

## HOW TO USE THE GUIDE

A six-step framework has been proposed to ensure that public health programme evaluations are useful, feasible, ethical, and accurate. [6]

1) **Engage all stakeholders** so that all stakeholders who are vital to the success of interventions are involved in a process that reaches out beyond external experts;

2) **Describe the situation** including needs, framework, context, existing activities, and resources**;**

3) **Make assessment plans**, including objectives, methods, and agreement describing how assessment plan will be implemented using available resources**;**

4) **Gather credible evidence** of defined quality and quantity, according to indicators obtained using proposed tools**;**

5) **Justify conclusions** according to standards, analysis and synthesis, interpretation, and judgements so that recommendations can be formulated**;**

6) **Ensure use** through design according to the needs of the evaluation users, preparation of future use of findings, feedback of information, follow-up, and dissemination**.**

Information collection for the purpose of assessment or evaluation is a process that should be understood by all participants, adapted to the local situation, limited to essential needs, conducted, analysed, and used appropriately. For this purpose, this rapid assessment and response guide was organized in six parts according to the proposed framework to evaluate public health programmes. For easy reference, the reader who is looking for a specific tool or a specific data collection instrument can find it rapidly using the table of data collection instruments (page 3).

## PROPOSED TIMELINE

This guide proposes an integrated approach for the rapid assessment of poor injection practices. For one country, the six phases of this rapid assessment should take approximately three weeks of the time of a principal investigator. A proposed timeline for the work plan of these three weeks is presented in Table 1.

*Table 1: Proposed agenda for a two-week rapid assessment of injection practices*

| Day | Week 1 | Week 2 | Week 3 |
|---|---|---|---|
| **Monday** | Meeting stakeholders | Fieldwork site 2 | Fieldwork site 4 |
| **Tuesday** | Meetings stakeholders | Fieldwork site 2 | Fieldwork site 4 |
| **Wednesday** | Preparation / travel | Travel to site 3 | Travel back |
| **Thursday** | Fieldwork site 1 | Fieldwork site 3 | Preliminary analysis |
| **Friday** | Fieldwork site 1 | Fieldwork site 3 | Initial debriefing |

| | | |
|---|---|---|
| **Week End** | Travel to site 2 | Travel to site 4 |

## 1- ENGAGE STAKEHOLDERS

At country level, achieving safe and appropriate use of injections requires a multidisciplinary three-element prevention [5] approach based upon:

1) Behaviour change strategies targeting patients and healthcare workers to reduce injection overuse and implement safe injection practices;

2) Provision of sufficient quantities of adequate injection equipment and infection control supplies;

3) Appropriate sharps waste management.

Because these activities are multidisciplinary, all stakeholders should be engaged to constitute a national coalition to prevent transmission of bloodborne pathogens from:

1) Transfusion of infected blood, blood components, or blood products;

2) Unsafe injection practices;

3) Other percutaneous or permucosal procedures conducted in healthcare or other settings.

While identifying stakeholders within and outside the Ministry of Health, care should be taken to integrate an injection safety initiative into other existing public health initiatives rather than creating a whole new independent programme.

The proposed steps to engage stakeholders include:

1) Identifying local stakeholders;

2) Getting stakeholders to recognize the problem;

3) Identifying potential resources;

4) Developing methods for ongoing sharing of information.

## IDENTIFIYING STAKEHOLDERS

Potential stakeholders should be identified through a review of planned, ongoing, or completed activities in the areas that are relevant to a safe and appropriate use of injection initiative (Table 2).

In the Ministry of Health, departments that may be involved include communicable diseases, blood transfusion safety, essential drugs, EPI, health promotion, family planning, healthcare service delivery, HIV/AIDS prevention, mother and child health, and nosocomial infections. Other government partners may include the Ministry of Education and the Ministry of Environment. Finally, other stakeholders, should be identified, including associations (e.g., consumers, physicians, nurses, dentists, traditional practitioners, and private healthcare providers), United Nations Organizations, Non Governmental Organization [NGOs], universities, trained pharmacists, drug sale clerks, as well as drug and injection devices manufacturing companies and their representatives.

*Table 2: Potential stakeholders at country level and their activities.*

| **Stakeholders** | | **Potential specific area of activities** |
|---|---|---|
| Ministry of Health | Communicable diseases | ✓ Hepatitis surveillance |
| | | ✓ HIV infection surveillance |
| | Blood transfusion services | ✓ Laboratory diagnosis |
| | | ✓ Education of blood donors |
| | Essential drugs | ✓ Rational use of injections |
| | | ✓ Procurement of syringes |
| | EPI | ✓ Procurement of AD syringes |
| | | ✓ Procurement of safety boxes |
| | | ✓ Sterilisation |
| | | ✓ Vaccine coverage surveys |
| | Health promotion | ✓ Community participation |
| | Family planning | ✓ Contraceptive injections |
| | Health services delivery | ✓ Financial and system incentives |
| | | ✓ Standards of care |
| | | ✓ Healthcare waste disposal |
| | HIV/AIDS prevention | ✓ Community participation |
| | | ✓ Community surveys |
| | | ✓ Infection control |
| | | ✓ Injection drug use |
| | | ✓ Monitoring and evaluation (MEASURE evaluation) |
| | Mother and child health | ✓ Community participation |
| | | ✓ Integrated Management of Childhood Illnesses (IMCI) |
| | | ✓ Community surveys |
| | Nosocomial infections | ✓ Universal precautions |
| | | ✓ Infection control committees |
| Ministry of Education | Medical schools | ✓ Healthcare worker training |
| | Nursing schools | ✓ Healthcare worker training |
| | Schools | ✓ Community participation |
| Ministry of Environment | Sanitation | ✓ Healthcare waste disposal |
| | Air pollution | ✓ Healthcare waste disposal |
| Associations | Public and private healthcare workers | ✓ Healthcare workers awareness |
| | Consumers | ✓ Consumer demand for safety |
| | | ✓ Community participation |
| United Nations organizations and programmes | WHO | ✓ Ongoing relevant activities |
| | UNAIDS | ✓ Monitoring and evaluation of national HIV/AIDS programmes (UNAIDS/WHO/MEASURE evaluation) |
| | UNICEF | ✓ Ongoing relevant activities |
| NGOs | According to availability | ✓ Rational use of drugs |
| | | ✓ Healthcare services delivery |
| Universities | According to availability | ✓ Applied public health research |
| | | ✓ Clinical research and training |
| | | ✓ Ongoing relevant activities |
| Pharmaceutical sector | Corporations | ✓ Appropriate marketing strategies |

## RECOGNIZING THE PROBLEM

Identified stakeholders should be approached from the perspective of their proposed, planned, ongoing, or completed activities, using the proposed guide for interviewing stakeholders (Instrument 1, Page 31). Awareness regarding injection safety should be developed on the basis of existing concerns and from the point of view of activities that they are already conducting and in which they already have ownership. Advocacy should facilitate recognition of the public health importance of the burden of disease associated with unsafe injection practices. Evidence-based advocacy material, including articles published in the *Bulletin of the World Health Organization* can be found on the resource centre of the Safe Injection Global Network (SIGN) World Wide Web site at http://www.injectionsafety.org.

## INVENTORY OF RESOURCES

In preparation for the constitution of a local team, available human, material, and financial resources should be identified. More specifically, research capacities (e.g., Universities, existing research projects), that may be used to obtain assistance in the collection of information during the assessment should be inventoried.

## SHARING INFORMATION

### WITHIN THE NATIONAL COALITION

Because the national team will be multidisciplinary and will involve various organizations and individuals, setting up ongoing mechanisms to share information as early as possible (i.e., during the initial assessment phase) is important. In addition to regular coordination meetings, new information technologies such as electronic mail may be useful to update the team about completed, ongoing, or planned activities.

### WITH THE INTERNATIONAL COMMUNITY

The SIGN weekly, moderated electronic mail forum is a useful way to receive updates regarding worldwide activities of the network (subscriptions at sign@who.int or on line at http://www.injectionsafety.org/html/joining.html). In addition, the SIGN Internet site may be used to access useful documents regarding the safe and appropriate use of injections (http://www.injectionsafety.org).

## 2- DESCRIBE THE SITUATION

Information gathered from identified stakeholders using Instrument 1 should be used to obtain a preliminary description of unsafe injection practices, their determinants, and their consequences.

The proposed steps to describe the situation include:

1) Organization of information using a generic framework;

2) Identification of available data as well as planned studies and surveys;

3) Modeling the expected burden of disease secondary to unsafe injection practices.

## ORGANIZATION OF INFORMATION USING A GENERIC FRAMEWORK

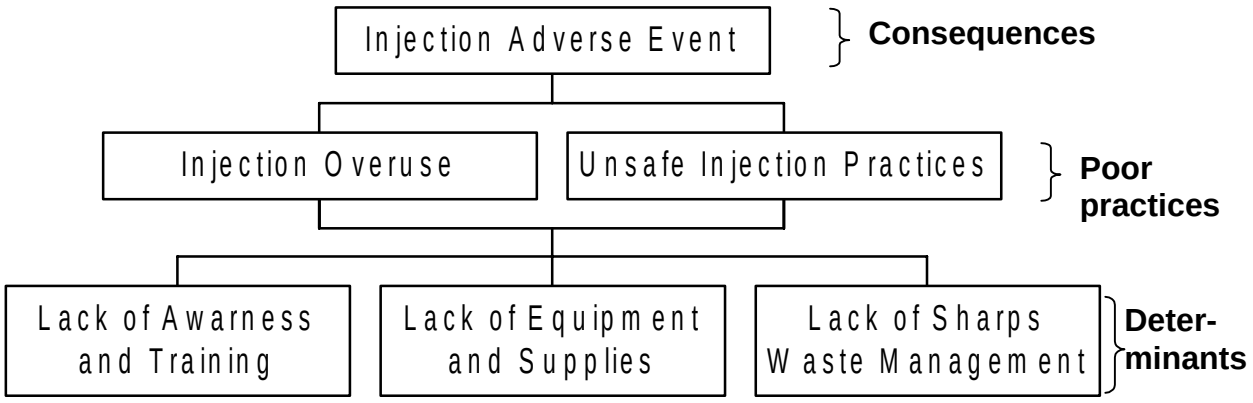
A simple, three-level generic framework (Figure 1) may be used as a basis for organizing the information obtained from the stakeholders to describe the situation. This generic framework describes injection practices according to three levels that include:

1) **The consequences among injection recipients** who present adverse events including infections with bloodborne pathogens, other infections, and injuries;

2) **Injection overuse and unsafe injection practices among injection providers**, including recipients themselves (self-injection), the family, formally trained healthcare workers, healthcare workers who were not formally trained, and informal injection providers, and traditional healthcare providers who interact with the recipient to administer unnecessary and/or unsafe injections;

3) **The determinants within a larger system** that includes ministries, NGOs, professionals, consumers, corporations (e.g., manufacturers of drugs or of injection equipment and their representatives), and universities that interact with injection recipients and injection providers to perpetuate poor injection practices.

*Figure 1: Proposed generic framework for unsafe injection practices, their determinants, and their consequences*




This proposed generic framework may be adapted as needed so that the members of the national team develop a common understanding of injection practices, their determinants, and their consequences.

## IDENTIFICATION OF EXISTING DATA, PLANNED STUDIES, AND SURVEYS

Stakeholders and key informants should be consulted to obtain and review information available regarding poor and good injection practices, their determinants, and their consequences (the three levels of the generic framework). In addition, planned population or healthcare facility-based surveys should be identified to create synergies during the assessment phase. The four joint UNAIDS/WHO/MEASURE evaluation packages[*] that are organized around population surveys, facility assessments, disease surveillance, and qualitative data, represent opportunities for collaborative work since assessment of injection practices also focuses on the same four components.

### CONSEQUENCES AMONG RECIPIENTS

Potential sources of information regarding infections with bloodborne pathogens, abscesses, and other injection adverse events include published and unpublished research reports (e.g., blood transfusion services reports regarding the prevalence of infections with bloodborne pathogens among first-time blood donors), infectious diseases surveillance, and EPI injection safety reviews (incidence of abscesses). In addition, the capacity of the national surveillance system to manage data for decision making should be evaluated as surveillance may be used to monitor the incidence of injection-associated infections. For more information regarding epidemiological methods to assess the association between unsafe injections and infections, see the additional tool to assess the association between injections and infections (Tool D).

### POOR AND GOOD PRACTICES AMONG PROVIDERS

Key informants might be the best source of much of this information in low income, low documenting countries. Besides published and unpublished research reports, there are other potential information sources regarding practices:

[*] Packages are to be published in July 2000.

## The OT8 indicator

Data may be available regarding the WHO/DAP OT8 indicator, the proportion of prescriptions that include at least one injection. [7] This indicator is a rapid method of assessing injection use in healthcare facilities. More information about the OT8 indicator can be found on Page 24.

## Population surveys

Population surveys (e.g., Multi-Indicator Cluster Surveys [MICS], Demographics and Health Surveys [DHS], community IMCI) constitute another potential information source to estimate the frequency of injections in the population.

Planned surveys that can be used to assess injection frequency

Planned community surveys should be identified with the objective of adding items regarding injection use to the questionnaire. Items that can included in the questionnaire of planned surveys should be borrowed from the tool to estimate the frequency of injections and identify injection providers (Tool B).

Already conducted surveys that may provide information on injection use

*IMCI community surveys*

IMCI community surveys are designed to evaluate 12 family-related key practices relating to IMCI. Community IMCI survey tools are currently under development.

*DHS*

DHS surveys are national surveys of women of reproductive age and their children under five years of children. DHS collect information of potential interest to estimate injection frequency, including:

1) Immunization history

2) Recent illnesses among children in the last two weeks (including healthcare seeking behaviour and use of injections to treat diarrhoea if applicable),

3) Family planing method of women,

4) Low risk behaviours to prevent HIV infection (including avoidance of injections).

Some countries may collect additional information relating to:

1) Behaviours that place at increased risk of HIV infection, including the number of injections received in the last three months and the person who administered the last injection received.

2) Malaria, including healthcare seeking behaviour during the last episode of malaria and medication used for treatment (without a specific reference to injections).

3) Health expenditure, which include information on healthcare seeking behaviour.

**INJECTION SAFETY**

Potential information sources regarding unsafe injection practices include EPI injection safety reviews, Global Alliance for Vaccine and Immunization (GAVI) assessments, and other facility surveys. Planned facility surveys should be identified with a view to adding items regarding injection safety to the data collection instrument. For more information regarding injection safety assessment and use of other facility surveys to integrate injection safety assessment, see the additional tool to assess injection safety (Tool C).

### DETERMINANTS IN THE SYSTEM

There are very few potential information sources regarding the behaviour and system determinants of poor and good injection practices include. A recent review article constitutes a potential starting point regarding determinants of unsafe injection practices. [8] National policies should be assessed for the existence of recommendations that may perpetuate injection overuse. Fox example, in many former socialist economies of Europe, Mantoux tests were recommended annually and all patients presenting with acute hepatitis were hospitalised. For more information regarding identifying the determinants of unsafe injection practices, see the additional tool to identify determinants of poor and good injection practices (Tool A).

## MODELLING THE EXPECTED BURDEN OF DISEASE

Estimates of the incidence of injection-associated infection with HBV, HCV, and HIV may be obtained a mathematical model. Although this model suffers from several limitations, [3] such estimates may be useful to provide estimates for local advocacy and further engagements of stakeholders.

The proposed model is a simple mass-action model (Figure 2). Calculations can be made using a hand calculator or a spreadsheet. The output of the model is an estimate of the annual incidence of injection-associated infections with HBV, HCV, and HIV. [3] This model should be constructed three times (once for each pathogen). Local estimates available should be used as input for the parameters of the model that include:

1) The estimated annual number of injections per person in the population;

2) The estimated proportion of injections administered with a syringe and /or needle re-used without sterilization;

3) The prevalence of active HBV, HCV, and HIV infection;

4) The prevalence of susceptibility to HBV, HCV, and HIV infection;

5) The percutaneous transmission potential of HBV, HCV, and HIV.* [9,10,11]

Estimates for these four country-specific parameters may be inferred on the basis of existing local data or extrapolated on the basis of information available from neighbouring countries or for a region. Sensitivity analyses may be made to evaluate the influence of parameters for which local estimates are imprecise.

* This parameter is identical for all country worldwide (HBV: 30%, HCV: 3%, and HIV: 3%).

*Figure 2: Equation of the Adam Kane model.*

$$P(\text{inf}) = 1 - \{1 - P(sus)xP(ex)xP(trans)\}^n$$

*P (inf) = Annual probability of infection with a given bloodborne pathogen for an individual in the population*

*P (sus) = Prevalence of susceptibility to the bloodborne pathogen in the population*

*P (ex) = Probability of exposure (prevalence of active infection in the population multiplied by the proportion of injections administered with a syringe and / or needle re-used without sterilization)*

*P (trans) = Probability of transmission of a bloodborne pathogen following a percutaneous exposure according to needlestick studies among healthcare workers*

*n = The annual number of injection per capita in the population*

## 3- MAKE ASSESSMENT PLANS

When the situation has been described on the basis of information already available, information needs should be defined for the three levels of the generic framework:

1) The consequences of poor practices among recipients;

2) The practices (injection overuse and proportion of unsafe injections) among providers);

3) The determinants of poor and good practices in the system.

Initially, information can be collected using rapid assessment methods. If more information is needed, in-depth assessments can be conducted using the four additional tools A, B, C, and D.

### RAPID ASSESSMENT

The rapid assessment methods consist in information collection from three different information sources:

1) Injection prescribers (e.g., physicians) with interviews and prescriptions reviews;

2) Injection providers (e.g., nurses) with interviews and observations in facilities where injections are administered;

3) The general population with interviews.

Data collection using the rapid assessment methods should take approximately two weeks of time to one single person.

### IN-DEPTH ASSESSMENT

If the information collected using the rapid assessment methods is not sufficient for decision-making, additional information may be collected for each of the three levels of the generic framework, additional studies may be conducted using the four additional tools (Figure 3).

*Figure 3: Proposed additional in-depth assessment tools to collect information regarding poor injection practices, their determinants, and their consequences.*

A) A tool to identify the determinants of poor and good injection practices (System level);

Tool A may be usefully applied to identify the behaviour and system determinants of poor and good injection practices when a broad behaviour change strategy targeting the population and healthcare workers is planned.

B) A tool to estimate the frequency of injections and identify injection providers (Provider level);

Tool B may be usefully applied to estimate the frequency of injections and identify injection providers in settings where injections received by the population are poorly characterised in terms of (a) overall frequency and (b) distribution across various injection providers. This is particularly relevant when injections given by informal injection providers and traditional healthcare providers are suspected to account for a high proportion of all injections.

C) A tool to estimate the proportion of unsafe injections (Provider level);

Tool C may be usefully applied to quantify safe injection practices when no information is available regarding the type of breaks in infection control practices that may lead to bloodborne pathogen transmission.

D) A tool to assess the association between injections and infections (Recipient level).

Tool D may be usefully applied to assess the association between injections and infections under the following circumstances:

- The existence or the strength of the association between injection and infection is uncertain;
- Local opinion leaders are not convinced of the burden of disease associated with unsafe injection practices in the country;
- The percutaneous procedures that lead to bloodborne pathogen transmission (i.e., unsafe injections, unsafe transfusions, and unsafe other percutaneous and permucosal procedures in medically related and other settings) and the relative prevention priorities that they should be assigned are unclear;
- The strength of the association between injection and infection has been chosen as an outcome indicator for prevention efforts.

## RAPID ASSESSMENT

### OBJECTIVES

The objective of the rapid assessment is to collect semi-quantitative information regarding injection practices.

### INFORMATION SOURCES

The rapid assessment methods consist in information collection through three different sources:

1) Injection prescribers (e.g., physicians): interviews of 20 prescribers and review of 100 prescriptions;

2) Interviews of 20 injection providers (e.g., nurses) conducted in association with observations in facilities where injections are administered;

3) Interviews of 40 persons from the general population.

### PROPOSED METHODS

#### Selection of field sites

Field visits should be conducted to four different districts, including (for instance):

1) The capital;

2) Two semi-rural districts chosen to be representative of the average conditions in the country;

3) A remote district thought to representative of the worse conditions that may be seen in the country.

#### Sample to be studied

In each study site, a convenience sample should be selected to include:

- 5 injection prescribers (e.g., in clinics, hospitals)
- 5 prescriptions from each of the 5 prescribers
- 5 injection providers (e.g., in clinics, at home)
- 10 persons drawn from the general population (e.g., in the street, on the market)

Often, injection prescribers and injection providers will be found in identical sites (e.g., clinics). Overall, the final sample should contain 4 x 25 = 100 prescriptions, 4 x 5 = 20

participants for prescribers and providers, and 4 x 10 = 40 participants for the general population. For the population, the sample may be structured to ensure representation of all ages and genders groups (Table 3).

*Table 3: Suggested age and sex distribution of the convenience sample of the population to ensure representation of all age and gender groups.*

| | Gender | | |
|---|---|---|---|
| **Age group** | **Male** | **Female** | **Total** |
| **Under 4 years of age** | 4 | 4 | 8 |
| **5-14 years of age** | 4 | 4 | 8 |
| **15-29 years of age** | 4 | 4 | 8 |
| **30-49 years of age** | 4 | 4 | 8 |
| **50+ years of age** | 4 | 4 | 8 |
| **Total** | 20 | 20 | 40 |



## Information collection

Information should be collected from injection prescribers, injection providers, and the population.

Data collection from injection prescribers

A standardized rapid assessment instrument is proposed to collect information from injection prescribers (See Instrument 2: Guide for interviewing injection prescribers, Page 33 ). In addition, a sample of five prescriptions should be studied from each of the five providers to calculate the proportion of prescriptions including at least injection (See Instrument 3: Sample data collection form for national drug policy indicator OT8, Page 34).

Tools to assess appropriateness of injections have been also proposed. These tools are based upon:

- The percentage of injection use for actual or hypothetical tracer conditions (cough, cold, and diarrhoea);
- The proportion of unnecessary injections calculated using standard treatment guidelines. [12]

Assessing the appropriateness of injections may be beyond the scope of rapid assessment. However, if needed, more information of the tools to assess appropriateness of injection use can be found elsewhere. [13,14]

Data collection from injection providers
A standardized rapid assessment instrument is proposed to collect information from injection providers (See Instrument 4: Guide to interview and observe injection providers, Page 35)

Data collection from the population
A standardized rapid assessment instrument is proposed to collect information from the population (See Instrument 5: Guide for interviewing the general population, Page 36). To allow comparison across settings where household sizes and age structure may differ, collection of information at the individual level is preferred to collection of information at the household level. [15,16]

## Data analysis

Analysis of quantitative data
Data should be analysed to compute the following critical indicators:

*Injection use*

Calculation of the OT8 indicator

WHO developed a set of structural, process, and outcome indicators to monitor national drug policies. [7,17] Among outcome indicators, indicator OT8 provides information regarding rational use of injections.

The objective of indicator OT8 is to assess the attainment of one of the major objectives of any national drug policy, which is the rational use of drugs. The indicator measures the overall level of use of injections. [7]

OT8 is defined as "the number of prescriptions with at least one injection, out of the total of prescription surveyed". It is obtained through a simple calculation. The numerator is obtained by adding the number of prescriptions with at least one injection (excluding immunizations [17]) in a sample of drug outlets. The denominator is the total number of prescription studied.

$$\textbf{OT8} = \frac{\textbf{Number of prescriptions with at least one}}{\textbf{Total number of prescriptions surveyed}} \textbf{ X 100}$$

The OT8 indicator can be calculated on the basis of prescription review (reference method) or prescribers interview (if prescription review is impossible).

Other indicators

- The mean number injections for prescriptions that include at least one injection (prescribers' data)
- The ratio of therapeutic / immunization injections (providers' and population data)
- The proportion of the population who received an injection in the last three months (population data)
- The average number of injections per capita and per year (population data)
- The distribution of injection providers for the last injection received (population data)
- The distribution of settings for the last injection received (population data)

*Injection safety*

- The proportion of injections given with a sterile syringe and needle (providers' data)
- The proportion of injections with collection of sharps in a sharps container (providers' data)
- The proportion of injections with adequate disposal of sharps (providers' data)
- The proportion of the population who recalled receiving their last injection with new, disposable injection equipment coming from a sealed packet or fitted with two caps (population's data)
- The annual incidence of needlestick among injection providers (providers' data)

*Determinants of injection practices*

- The proportion of persons reporting the possibility of injection associated HBV, HCV, and HIV infection (prescribers, providers, and population data)
- The proportion of prescribers reporting patients' preference for injections (prescribers' data)
- The proportion of patients reporting preferring injections (population data)
- The proportion of injection providers reporting sufficient supplies of injection equipment (providers' data)
- The proportion of injection providers reporting sufficient supplies of sharps containers (providers' data)
- The proportion of injection providers reporting access to a sharps waste disposal facility (providers' data)

Analysis of qualitative data

In addition to the quantitative analysis of the indicators mentioned above, qualitative analysis of the qualitative data is important as it allows stakeholders can come to understand how injections interact with the health belief model of their healthcare providers and of their local population.

- Reported conditions for which injections are used (prescribers)
- Reported medications administered most commonly (prescribers)
- Other information collected on free fields on in addition to the items of the standardized questionnaire.

## IN-DEPTH ASSESSMENT

Four additional tools available from the SIGN secretariat may be used to conduct in-depth assessments of injection practices.

**A TOOL TO IDENTIFY THE DETERMINANTS OF POOR AND GOOD INJECTION PRACTICES**

Tool A consists in a set of guides to conduct focus group among injection prescribers, injection providers, and injection recipients. Collection of information using Tool A should take approximately two weeks of field work for a focus group moderator and a note taker and additional time for analysis.

**A TOOL TO ESTIMATE THE FREQUENCY OF INJECTIONS AND IDENTIFY INJECTION PROVIDERS**

Tool B consists in a guide for a population survey. Collection of information using Tool B should take approximately two to three weeks of fieldwork for a team and additional time for analysis.

**A TOOL TO ESTIMATE THE PROPORTION OF UNSAFE INJECTIONS**

Tool C consists in a healthcare facility survey guide. Collection of information using Tool C should take approximately three weeks of work for a team leader and two weeks of fieldwork for four supervisors, four field workers, and four drivers.

**A TOOL TO ASSESS THE ASSOCIATION BETWEEN INJECTIONS AND INFECTIONS**

Tool D consists in suggested framework to conduct epidemiological studies to assess the association between injections and infections. Collection of information using Tool D usually requires substantial time and expertise from a multidisciplinary team and a capacity for the diagnosis of acute viral hepatitis.

## 5- JUSTIFY CONCLUSIONS

When the data collection process has been completed, overall results should be summarized according to the adapted generic framework (See "2- Describe the situation", Page 15). The report should describe and report the elements indicating that injection overuse and / or unsafe injection occur, using quantified indicators when available. The identified determinants of poor and good practices as well as the injection-associated adverse events should be detailed.

Recommendations for the development of a safe and appropriate use of injection strategy should be formulated according to the results of the assessment and using the same collaborative group that worked together on the assessment. This process helps to provide stakeholders with a more refined understanding of their situation so that they are in a better position to take initiatives and intervene creatively within their context:

1) The behaviour change strategy targeting healthcare workers and patients should be designed on the basis of the system and behaviour determinants of poor and good injection practices. Lack of guidance among injection prescribers may be improved by standard treatment guidelines as in a pilot intervention in Tanzania [18]. In Indonesia where qualitative assessment indicated that injection overuse resulted from a lack of communication between patients and providers, interventions based upon interactional group discussions between patients and providers may be effective [19]. Following an qualitative assessment in Romania, waiting rooms in public clinics were used as strategic access point for posters suggesting that "your health is not a game, your body is not a target", that most conditions could be treated with oral medications, and that patients should discuss injection needs with physicians [Viorica Ghiorghiu, Institute of Public Health of Bucharest, personal communication];

2) Groups of injection providers to be targeted by prevention activities should be defined on the basis of the distribution of injection received by the population according to injection providers;

3) Efforts to implement safe injection practices should be tailored according to identified unsafe practices, equipment and supplies shortages, and waste management issues. In Burkina Faso, making injection equipment available in community pharmacies at low price using a cost recovery scheme was associated with a dramatic reduction of re-use of disposable injection equipment between 1995 and 2000 [20,21];

4) Support for safe and appropriate use of injection activities should be determined on the basis of relative priority ranking deserved according to the burden of disease attributable to unsafe injection practices.

### FEEDBACK

The initial assessment of injection practices is the first step towards managing data for decision making in a safe and appropriate use of injection strategy. Results of the initial assessment should be communicated to all stakeholders, including the future audience of the behaviour change strategy (the population and healthcare workers).

### ADVOCACY FOR ACTION

To ensure long-term usefulness of the initial assessment, the collaborative structure between all stakeholders should be maintained. Because these results will be used to the extent that stakeholders are persuaded that this is a high enough priority activity to be on their agenda, assessment results should be used for advocacy. Within the SIGN, the proposed three components of an advocacy strategy are:

1) A summary document describing the full social and economic dimension of poor injection practices. This document, based upon local information, should emphasize that safe and appropriate use of injections is ultimately not only about safe and appropriate use of injections, but also about (a) reducing the out-of-pocket expenses wasted in unnecessary injections, (b) preventing a large quantity of chronic viral infection leading to substantial disability and death, and (c) strengthening health systems through better quality of healthcare services delivery;

2) Communication with the general public (e.g., through newspaper article and television reports) to present poor injection practices situations;

3) Demonstrating that poor injection practices may be eliminated through the provision of local and international success stories.

### MONITORING IMPACT

Using the initial assessment results as a baseline measure, indicators identified as critical by all stakeholders during the initial assessment should continue to be used for ongoing collection of information. Intervention evaluation should then be based upon routine collection of information on process indicators (the frequency of injections and the proportion of injections that are safe) and outcome indicators (the incidence of injection-associated infections).

### PROCESS INDICATORS OF INJECTION FREQUENCY AND SAFETY

## Process indicators of injection frequency

While injection frequency surveys are time-consuming and could not be conducted regularly to monitor impact, the proportion of outpatient visits followed by an injection is an indicator that is easy to use and has been used by WHO for many years.

## Process indicators of injection safety

A simplified version of the injection safety surveys data collection instrument such as proposed in this toolbox (see Tool C), possibly restricted to indicators found to be problematic, can be used for routine data collection during supervisory visits to monitor the proportion of unsafe injections.

### OUTCOME INDICATORS OF INJECTION-ASSOCIATED INFECTIONS

To evaluate the impact of safe and appropriate use of injection policies, epidemiological analysis should be conducted to evaluate the association between injections and infections during the time period when the policy was implemented. Thus, cases of recent infection (e.g., acute hepatitis B or C) should be investigated so that recent referent exposure period can be explored in search of potential risk factors for infection.

Although repeated case-control studies and ongoing cohort studies may be used, viral hepatitis surveillance (see Tool D) is the most cost-effective way to routinely collect, transmit, and analyse data on recent acute hepatitis cases for the purpose of evaluating the impact of safe and appropriate use of injection policies.

**UNRESOLVED ISSUES TO BE ADDRESSED DURING PILOT TESTING**

- Should a limited set of "tracer" conditions be used to assess rational prescription of injections by injection prescribers and popularity of injections among recipients?
- How should the origin of injectable and injection equipment be studied?
- Is there room in this toolbox for a checklist to evaluate the national authority that has regulatory power in the field of injection devices and / or injectable medications?
- How should costs be studied (e.g., cost of injection equipment, cost of injectable medications, costs of outpatient visits with / without prescription of an injection)?
- Are more details necessary in terms of recommendations for data analysis in this toolbox (e.g., empty data table etc.)?
- Should there be a different in-depth data collection instrument to assess unsafe injection practices and its determinants in healthcare facilities?

## APPENDIX: DATA COLLECTION INSTRUMENTS

### INSTRUMENT 1: GUIDE FOR INTERVIEWING STAKEHOLDERS

1. Please describe your activities in the field of public health and / or healthcare delivery?
   - Do you conduct activities in the area of assessment and evaluation?
   - Do you conduct activities in the field of behaviour change, health education, or IEC?
   - Do you provide medical equipment or supplies to healthcare facilities?
   - Are you involved in healthcare waste management?

2. Who administer injections in your country?
   - Nurses?
   - Physicians?
   - Dentists?
   - Informal providers?
   - Others?

3. Is injection safety a problem in your country?
   - Is yes, what are the problems?

4. Are injections overused in your country?
   - If yes, what are the attitudes among patients that contribute to this?
   - What are the attitudes and other factors that lead to such behaviours among healthcare workers?

5. Are syringes and needles re-used without sterilization in your country?
   - If yes, what are the attitudes and other factors that contribute to the absence of a demand for safe injections among patients?
   - What are the attitudes and other factors that contribute to unsafe practices among healthcare workers?
   - Do shortages of injection equipment supplies contribute to unsafe injection practices?
   - Do waste management problems contribute perpetuate re-use of injection equipment in the absence of sterilization? If yes, how?

6. Are syringes and needles immediately discarded in a sharps box in your country?
   - If no, why not?
   - Potential probes:
     - What are the attitudes among healthcare workers that cause that?
     - What are the lacks of supplies that cause that?

7. Are syringes and needles appropriately disposed of in your country?
   - If not, why not?
   - Potential probes:
     - What attitudes perpetuate this situation?
     - What types of constraints perpetuate this situation?

8. Are you aware of specific information sources regarding injection practices, their determinants, and their consequences in your country? (If yes, list)
   - If yes, can you list them?

9. Are you aware of planned, ongoing, or completed studies and / or surveys regarding injection practices, their determinants, and their consequences in your country?

- If yes, can you list them?

10. Are any of the activities you do relevant to the area of safe and appropriate use of injections?
    - If yes, can you list them?

11. What do you think should be done to ensure safe and appropriate use of injections in your country?

12. Who should be involved in this effort? To do what?

13. What could be your role in a national initiative for the safe and appropriate use of injections?

**INSTRUMENT 2: GUIDE FOR INTERVIEWING INJECTION PRESCRIBERS**

*Greetings! As we are working here to understand how injections are used, I would like to ask you a few questions about how you prescribe injections. The information I will collect will be recorded anonymously and I will not write your name on this form. As we go through the questionnaire, please feel free not to answer if you don't wish to give additional information if you want.*

| | |
|---|---|
| 1. How many patients do you usually care for during an average week | ___ Patients |
| 2. Of these, for how many would you usually make a prescription that includes at least an injection? | ___ Patients |
| 3. For those to whom you prescribe at least one injection, how many injections would the total treatment typically include? | ___ Injections |

4. What are the three diseases for which you prescribe an injection most often?

1- 2- 3-

*Comments:*

5. What are the three injectable medications that you prescribe most often?

1- 2- 3-

*Comments:*

6. When you prescribe an injection, who usually give the injections to the patients?

1- 2- 3-

*Comments:*

7. Do you think that patients usually prefer injections for the treatment of diseases that could be treated by mouth?

1- Yes 2- No 3- Don't know

*Comments:*

8. Could you name three diseases that may be transmitted through unsafe injections?
*(Circle when spontaneously mentioned)*
Others: List:

1- HIV 2- HCV 3- HBV

9. Do you think that you prescribe too many injections?

1- Yes 2- No 3- Don't know

*Why:*

10. What would lead you to prescribe less injections?

*Comments:*

**INSTRUMENT 3: SAMPLE DATA COLLECTION FORM FOR NATIONAL DRUG POLICY INDICATOR OT8**

(This form was adapted from a WHO/DAP document [7])

| No. | Drug prescribed | Anti-biotic | From EDL* | Not from EDL | Injection † |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |

* Essential drug list

† Tick if yes.

**INSTRUMENT 4: GUIDE TO INTERVIEW AND OBSERVE INJECTION PROVIDERS**

*Greetings! As we are working here to understand how injections are used, I would like to observe how you give injections and to ask you a few questions. Please feel free not to answer if you don't wish or to give additional information if you want. The information collected will be recorded anonymously and I will not write your name on this form.*

| | | |
|---|---|---|
| **Observation of an injection:** | | |
| 1. Use of new disposable syringe and / or needle or sterile sterilizable syringe | 1. Yes | 2. No |
| *Comments:* | | |
| 2. Immediate discarding of sharps in a sharps box | 1. Yes | 2. No |
| *Comments:* | | |
| 3. Two-hands recapping | 1. Yes | 2. No |
| *Comments:* | | |
| 4. Appropriate disposal / destruction of sharps | 1. Yes | 2. No |
| *Comments:* | | |
| **Interview of the injection provider:** | | |
| 5. How many injections do you give in one week? | __ Vaccinations | __ Others |
| 6. Could you name three diseases that may be transmitted through unsafe injections? *(Circle when spontaneously mentioned)* | | |
| 1. HIV | 2. HCV | 3. HBV |
| 7. How many needlestick injuries have you had during the last 12 months? | ___ Injuries | |
| *Comments:* | | |
| 8. How many doses of hepatitis B vaccine have you ever received? | ___ Doses | |
| 9. Do you have sufficient quantities of injection equipment to apply the one syringe and needle/ one injection rule? | | |
| 1- Yes | 2- No | 3- Don't know |
| *Comments:* | | |
| 10. Do you have sufficient quantities of sharps boxes to dispose of sharps safely? | 1. Yes | 2. No |
| 1- Yes | 2- No | 3- Don't know |
| *Comments:* | | |
| 11. Do you have access to a sharps waste disposal facility to dispose of your sharps waste | 1. Yes | 2. No |
| 1- Yes | 2- No | 3- Don't know |
| *Comments:* | | |

**INSTRUMENT 5: GUIDE FOR INTERVIEWING THE GENERAL POPULATION**

*Greetings! As we are working here to understand how injections are used, I would like to ask you a few questions. Please feel free not to answer if you don't wish. The information collected will be recorded anonymously and I will not write your name on this form.*

| |
|---|
| 1. During the last three months that is between <date> and <date> did you receive an injection or an IV infusion? (Prompt) The potential persons who may have given you an injection or an IV infusion include your doctor, your nurse, your dentist, a relative, any other person or caregiver, or yourself.<br>1 - Yes If yes, how many? ____ 2- No |
| *2.* (If yes to question A) How many of these injections were given by a health care worker for the purpose of a vaccination? _____ |
| 3. Can you remember the last injection you have received?<br>1 – Yes 2 - No If yes, when was it: _____ |
| 4. (If yes to question 3) Can you remember who gave you this last injection?<br>1 – A medical doctor 2- A nurse 3- A dentist 4- A traditional healer<br>5- Someone else 6- Me, myself 7- I don't remember |
| 5. (If yes to question 3) Can you remember where you received this last injection?<br>1- Clinic 2- Hospital 3- Dental office 4- Home 5- Don't know |
| 6. (If yes to question 3) Can you remember where the needle and the syringe that were used to give you this last injection came from?<br>1 – From a blister package 2- It was fitted with two caps 3- From a pot of tepid water<br>4- From a sterilizer 5- Other (specify)_____ 6- I don't know/ remember |
| 7. (If yes to question 3) Can you remember what you paid for this injection? ____ Total<br>____ For the medication ____ For the syringe / needle __ For the injection service fee |
| 8. Have you ever been accidentally stuck by a injection needle that was left in the garbage or in the environment:<br>1 – Yes ____ Times 2 - No 3- Don't remember |
| 9. When you are sick with fever, what is the treatment that your prefer to receive?<br>1 – An injection 2 - An oral medication 3- I don't care |
| 10. Do you think that dirty syringes can transmit diseases?<br>1 – Yes 2 - No 3- I don't know |
| *11. If yes, which* (Circle when spontaneously mentioned)<br>1- HIV 2- HCV 3- HBV<br>3- Abscesses 4- Other (specify):_____ |

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WORLD HEALTH ORGANIZATION (WHO)

BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL II (BASICS II)

SAFE INJECTION GLOBAL NETWORK (SIGN)

# TOOL "A" TO IDENTIFY DETERMINANTS OF POOR AND GOOD INJECTION PRACTICES

THIS DOCUMENTS IS PART OF A TOOLBOX TO ASSESS AND EVALUATE INJECTION PRACTICES. THE COMPLETE TOOLBOX INCLUDE THE RAPID ASSESSMENT AND RESPONSE GUIDE AND FOUR ADDITIONAL TOOLS (A, B, C, AND D)

This toolbox addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS, Arlington, VA, USA in March 2000. It constitutes a dated draft circulated for comments and suggestions. Although it is made widely available at an early stage, it is not yet intended to be a "how-to" manual for field use. Later versions of this document will be adapted for wider readership level once consensus has been reached on broad concepts and after field testing.

Comments and suggestions should be directed to the Secretariat of the Safe Injection Global Network (SIGN), World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, Geneva 27, Switzerland 1211. Fax +41 22 791 4836. E-mail: sign@who.ch.

| **Intended use and proposed timeline for this document** | |
|---|---|
| Preparation of draft 1 by selected consultants | February 22, 2000 |
| Review of the draft 1 by a group of experts and preparation of draft 2 | April 30th, 2000 |
| Review of draft 2 by workshop participants to prepare draft 3 | May 31st, 2000 |
| Field testing of draft 3 in few countries to prepare draft 4 | September 1st, 2000 |
| Wider dissemination of draft 4 for broad use and ongoing feedback | 2000-2002 |
| Preparation of a final version after two years of feedback from the field | End of 2002 |

## A- TOOL TO IDENTIFY DETERMINANTS OF POOR AND GOOD INJECTION PRACTICES

### BACKGROUND

Focus group discussions are useful tools for collecting qualitative information on attitudes and practices regarding injections. [1,2,3,4,5] They can be used to explore collective norms and practices regarding injections and to understand people's perceptions of advantages and risks associated with injections. Focus group discussions are used to formulate hypotheses or to better understand quantitative data. They produce rich data in a limited amount of time although the analysis of this data can be time consuming. Ideally focus groups are combined with other data collection methods, for instance in-depth interviews with key informants (community leaders, popular injection providers, medical stock keepers etc) to allow for a greater depth of data or surveys to quantify information. Although this tool does not contain any guide to conduct them, more information regarding in-depth interviews can be found elsewhere. [6]

The focus group guides and methods presented in this document are intended to help people who wish to carry out injection assessments in their countries. A number of methods are necessary to gain an understanding of the problem of unnecessary and unsafe injections in specific contexts. However, the focus group guides described will enable health planners to understand how injections and injection safety are perceived by patients, communities, prescribers, different types of injection providers, auxiliary staff / workers handling healthcare waste. Such an understanding is crucial in order to frame information, education and communication interventions and to adapt medical knowledge and practices to identified needs. Information from focus groups can also be used to inform the design of other data collection methods or provide additional information on a certain subject. Focus groups should therefore be conducted early on in the assessment exercise so that the obtained data can be use to phrase specific questions in other tools such as survey instruments or observation guides.

### OBJECTIVES

The objectives of the focus group sessions with communities and patients are:

1) To explore the socio-cultural meaning of injections (including identifying local terms for "injection" and for the various injection providers);

2) To identify the people's perception of the therapeutic rationale behind the injections;

3) To understand the direct and indirect costs of injections;

4) To understand people's perception of injection safety.

The objectives of the focus group sessions with injection prescribers and providers are:

1) To understand prescribers' therapeutic rational and other motives for prescribing injections;

2) To explore the prescribers' and provider's understanding of overuse and safety issues relating to injections;

3) To understand how the working environment of the prescriber and provider may impact on the prescription and safety of administered injections.

The objectives of the focus group sessions with auxiliary workers / workers handling medical waste are:

1) To understand the staff perception of the risks related to accidental needlestick injuries;

2) To understand the reasons why healthcare waste is not disposed of adequately;

3) To understand which risk may occur in the community.

The focus group guides included in this document include:

1) The instrument for patients and communities (Instrument 1, page 16);

2) The instrument for injection prescribers (Instrument 2, page 20);

3) The instrument for injection providers (Instrument 3, page 16);

4) Instrument 4: Guide for focus group discussions on injections (auxiliary staff / workers handling healthcare waste), page 30.

These tools must be adapted to local capacity and need before application. The training and tasks of moderators and note-takers working with focus groups on injections as well as suggestions for the analysis of focus group data, report writing, and recommendations are described below (page 3 and 9, respectively).

## GUIDELINES FOR MODERATORS OF FOCUS GROUP DISCUSSIONS ON INJECTIONS

### PURPOSE OF FOCUS GROUP DISCUSSIONS

A focus group consists of a number of people brought together to discuss a certain number of subjects. The participants will be selected according to certain criteria but it is important that they feel at ease with each other. A moderator and a note-taker will normally guide the focus group discussion.

In the context of injection assessments the focus group discussions will be used to explore the attitudes and practices of patients, communities, injection prescribers, injection providers, and auxiliary staff / workers who handle healthcare waste with regard to the use and safety of injections. The purpose of the different focus group discussions is to stimulate discussions between the participants, not between the moderator and the participants. The results from the focus group discussions will be used to frame and define the interventions.

### RECRUITMENT OF MODERATORS AND NOTE-TAKERS

#### Moderators

Moderators need to have strong interpersonal skills and a good degree of confidence and sensitivity. This is very important for their ability to conduct focus group discussions. They need to know the local culture and language well and some previous experience with focus groups is an advantage. In addition, to conduct focus groups among injection prescribers and injection providers, they need a certain level of expertise in rational use of medications and in infection control practices.

## Note takers

Note-takers should also have good knowledge of the local culture and language. They should be able to take extensive and comprehensible notes.

### TRAINING OF MODERATORS AND NOTE-TAKERS

The training of the moderators and note-taker is very important. First of all the moderators and note-takers need to understand the purpose of the research and how the various subjects and questions will help in fulfilling the purpose of the research. They need to be familiar with the culture of the participants so that they can phrase their questions in meaningful ways and understand subtle nuances in answers, such as non-verbal communication. Next they need to understand that they are only facilitators of the group dynamics and that their primary role is to activate the participants. They need to be sensitive to status differences between participants and possible unforeseen biases in the venue chosen for the focus group discussion.

The training can be done in different steps. The below listed steps will achieve a sense of ownership as well as appropriate training of the moderators and note-takers. It takes approximately seven days including field practice. It is important that an experienced social scientist conducts the training as mere distribution of guidelines will be insufficient to train the group of moderators and note takers.

## Day 1

A workshop is a good way of starting the initial thorough discussion of the purpose of the research, the background, methods and expectations of moderators. The participants should define the various key research themes or questions through a collective brainstorming interactive process. This exercise will shape the specific research tools and the later analysis of collected data. Translations of key terms into local language should be agreed upon between the principal investigator and the various moderators.

## Day 2

Moderators and note-takers should be involved in the development of the focus group guides if possible. This helps them understand the objectives of the research and creates a sense of ownership. The major research questions have already been defined on day 1 and the workshop participants should now use these research questions to develop the actual research tools. The type of research tools will depend on the practicalities of the field. If for instance participants feel that it will not be possible to have focus group discussions with patients in private facilities, then they will need to develop exit interviews for patients instead.

It is useful to divide the participants into two smaller groups where one group develops tools for patients and communities and the other group develops tools for injection prescribers and providers. When this process has been completed the working groups can take a look at the SIGN research tools to see if there is anything that they wish to add to their guides and questionnaires. It should be stressed that during the field test other questions may be added as interviewers and moderators increase their understanding of the purpose and constraints of the research. A few role-plays should be conducted in which the moderators and note-takers try to moderate group discussions as well as try to play the role of participants in these discussions. The principal investigator should observe and advise the moderators on their conduct of these role-plays.

## Day 3

This day combines the field training of moderators and note-takes with a field test of the guides. The workshop participants are divided into smaller teams of two people in such a way that the two team members have different experiences with the development of the tools. In other words, one team member comes from the group that developed the questionnaires for patients and community, and the other is from the group that work of the questionnaires for prescribers and dispensers. The principal investigator supervises the proceedings and everybody meets at the end of the day to discuss problems in application and compare notes. It is also important to start the preliminary analysis at this stage. This allows participants to reflect on their data and to identify new leads that should be followed up during fieldwork the next day.

## Day 4

Another day of supervised field training. If all goes well there is no need for an extra day of field training. At the end of day 4 the participants meet again to continue the data analysis and to revise the questionnaires in the light of the field experiences.

## Day 5 and 6

Day 5 and 6 are devoted to the finalization of the data analysis and the identification of major conclusions and new leads. This is a process that involves the entire group and often a lively discussion about the interpretation of results will occur. Specific and feasible interventions are defined for each major conclusion in terms of the contents of messages, the vehicles for intervention and the resources available for implementation.

## Day 7

The final task is to define the audiences for the final report and how it will be used: for advocacy, fundraising, to document a problem etc. The outline for the report is discussed and agreed upon. The practical implementation plan for the interventions is drawn up with a timeframe and indication of who is responsible for following up. If further research is needed to validate conclusion then this should also be identified with a time frame.

### PRE-TEST OF FOCUS GROUP GUIDES

Pre-testing the focus group guides before the actual field research starts is important. The guides can be pre-tested for each type of respondents on similar respondents outside the research area but within the same cultural and social circumstances. At least one and preferably two pre-tests of guides should be conducted. The guides should be revised according to the results of the pre-tests. As explained above, pre-testing of the guides and training of moderators and note-takers can be combined.

### EQUIPMENT

The following equipment will be needed in each focus group discussion:

- The focus group guide

- A tape note-taker with labelled tapes (two extra tapes should be available)
- Extra batteries or batteries as a back-up
- Note block and pens
- Refreshments or snacks for participants

**PREPARING FOCUS GROUP DISCUSSIONS**

## Recruitment

Recruitment of participants in the community

*Homogeneity*

As a general rule, participants in injection oriented focus groups should be of the same gender, of the same socio-economic status, and speak the same language. When a group seems to be heterogeneous, it can be broken down in smaller, homogeneous groups.

*Sampling*

Convenience sampling

Focus group on patients may be assembled using a convenience sampling technique (e.g., The selection of a number of patients who are waiting in specific health facility or patients who are just leaving the facility). While this is an easy way to sampling, this type of sampling may be biased. Waiting patients may have certain characteristics such as proximity to the health facility or a desire for a specific type of treatment for which the facility or provider is known. Such biases are often unavoidable when limited time is available for the assessment but they should be made explicit in the report.

Random sampling

Random sampling is the best way to sample participant for focus groups. I should be preferred whenever possible. Community members may also be assembled using a random sampling strategy. This could be done for instance by inviting a household member of every tenth house of a certain community to be present at a meeting at a certain time and date.

Recruitment of participants among injection prescribers, injection providers, auxiliary staff/ workers handling healthcare waste

There are different scenarios for selecting the participants of focus groups among prescribers and providers. In most cases focus groups are conducted with prescribers of the same status. While nurses and midwives can discuss together; it is probably better to conduct discussions with doctors separately. Otherwise the nurses and midwives may be intimidated. Providers of injections should also be of the same category to the extent possible. This category may include janitors, cleaners and general helpers at the health facilities. It may also include informal injection providers (e.g., pharmacy assistants, shop assistants) and traditional healthcare providers (e.g., traditional healers). Other options in the selection of prescribers are to include each type of prescriber (except doctors) so that different perspectives on injections are heard, or to mix community members with injection providers in some focus groups to identify differences between the two groups. If the plan is to conduct a large number of focus group discussions if it is thought that this option might elicit greater depth of comment, providers and prescribers can be segmented to constitute homogeneous groups of nurses, midwives, janitors, shop assistants etc. If several health facilities and informal settings are providing the sampling frame then it should be possible to put together a random sample of prescribers and providers. If the number of health facilities in the study is limited then convenience samples may be more

feasible. The sampling decisions should be made in the context of the specific objectives and resources of the assessment and they should be made explicit in the report so that possible biases can be identified.

## Focus group size

Each focus group should consist of 6 to 12 people, not including the moderator and note-taker. They number will vary according to the setting and the objectives of the assessment. Normally one or two invited participants will not come or may leave during the discussion. There may also be situations where outsiders wish to join in the discussion. This must be handled with diplomacy as rejecting these outsiders may create a tense environment and therefore impact of the quality of the data from the focus group. Sometimes it is better to let these outsiders join. In general, if the objectives of the research are narrowly defined it may be better to have fewer rather than more participants. Using a site that is removed from traffic flow can help alleviate the problem of outsiders joining somewhat.

## Number of focus group to be conducted

In terms of the number of focus group discussions to be conducted it depends on the area covered and the variation in answers between the various types of groups as well as the time and resources allotted. If several areas are covered, such as a rural, peri-urban and an urban setting, then of focus group discussions with patients, community, injection prescribers, injection providers, and auxiliary staff/ workers handling healthcare waste must be conducted for each area. Each type of focus group should be conducted at least two to four times. If data from the groups is consistent and no new hypotheses have emerged to be tested, then there is no need to conduct any more focus group discussions.

### VENUE

It is important to choose a convenient and neutral venue for the focus group discussion. If patients are waiting in a waiting room they can be asked to join a focus group discussion in a separate private room or at a nearby meeting place. Community members may meet in a local school after school hours or another venue that is convenient for them. Injection prescribers, injection providers, and auxiliary staff / workers handling healthcare waste may be asked to meet after hours in the health facility or another appropriate local place. A refreshment (not alcohol) or snack should be offered to the focus group participants to appreciate the time given by people. In general it should be avoided that people have to travel long distances to get to the focus group meeting place, as many people will not show up. If people do travel they must be compensated for their travel costs. In some cases, in rural area, travel will have to be provided.

### MODERATION OF FOCUS GROUP DISCUSSIONS

## The moderator

The moderator's role is to ensure that the participants are relaxed and that everybody is contributing to the discussion. Before the discussion starts the moderator must ensure that the participants are seated comfortably and the moderator and note-taker are seated at the same level as the participants. The moderator can make efficient use of his/her own body language and the group seating arrangement to guide the discussion, for example by sitting where he/she

can use eye contact to encourage participation by more reticent group members, or where he/she can most easily control more verbose and domineering group members.

The moderator guides the participant through a list of subjects that can be covered in whatever order is natural. Questions aim at illustrating group norms and behaviour and should not try to identify individual behaviour unless participants bring such examples up themselves. If some group members speak too much while others are silent, the moderator must take statements from the dominant members and try to activate the more passive people by asking them what they think about the statements, if they agree or if they can add something to the statements.

The moderator probes with additional questions or examples when necessary. Although the guides contain a large number of probes in the form of questions, care must be taken not to turn the discussion into a question and answer session. Probes should stimulate discussion or statements by the participants. It is also important that the moderator appears to be neutral and does not in any way dominate or influence the discussion. There are no "right or wrong" answers, only opinions that are equally valid. It is important to follow up on any contradictions that may occur in the statements of participants or disagreements between participants. Such disagreements or inconsistencies often provide important insights.

The focus group discussion should not last more than an hour or maximum 90 minutes and the moderator must be attentive towards signs of fatigue or boredom of the participants. If the participants seem tired, the moderator may wish to shorten the list of questions for the next focus group session. After the end of the focus group session, the moderator should stay for a while in case any of the participants wish to add or clarify something in private.

## The note-taker

The note-taker assists the moderator by taking careful and extensive notes during the discussion. He or she must note general themes and the group reactions and consensus. If there are particularly interesting statements, they should be written down using the words of the respondent. The note-taker is also responsible for tape-recording the discussions. Participants need to be assured that this tape recording will be kept confidential and that they have a right to refuse to participate. The note-taker will observe the group dynamics carefully and make notes about the interaction and the body language of the participants. The note-taker must also describe the setting in which the discussion is taking place and whether there are any factors that may introduce a bias into the answers (for instance the presence of a high level person or supervisor).

### QUESTIONAIRE GUIDES

Questionnaire guides for the proposed focus groups are proposed in Instrument 1, Page 16; Instrument 1, Page 20; in Instrument 3, Page 25; in Instrument 4, Page 30, and in Instrument 5, page 31).

### ANALYSIS

The analysis can be conducted in several ways depending on the qualifications of the researchers and the time and resources available. If resources are not a constraint then all focus groups can be taped and transcribed and analysed. If this option is chosen then it is important that the moderators and note-takers transcribe the tapes of the focus groups immediately after the focus group session while they can still remember the interaction. If there is a need to

translate the transcripts then this should be done by a translator in collaboration with the moderators and the principal investigator.

If human and time resources are limited then it may be better to listen to the tapes while improving on the notes taken during the focus group discussion. The notes will then be reviewed and analysed and the tapes will only be used for back up.

A third option is not to tape the focus group discussions at all but to discuss and consolidate the notes between note taker and moderator immediately after each focus group discussion. Minor details may be lost but the overall conclusions and observations will be captured. Likewise striking quotes can be captured this way.

## GUIDELINES FOR ANALYSIS OF DATA FROM FOCUS GROUP DISCUSSIONS ON INJECTIONS

### INTRODUCTION

The analysis of qualitative data is based on the inductive research method. [1,3 ,7]This means that hypotheses will be formed based on the analysis of the data. The outcome of such inductive research is a hypothesis that theoretically has to be proven or disproved through other types of qualitative or quantitative research. This is different from quantitative research in which a hypothesis is formulated before the research and the data analysis is used to test the validity of the hypothesis. Qualitative research is therefore particularly useful to explore new areas or to determine perceptions and values that inform the actions of groups of people. It aims at understanding issues from the respondents' point of view taking into consideration their specific social and cultural contexts. It is also worth adding that qualitative research such as focus group discussions can yield high-quality intervention-oriented data in a limited time.

The analysis of data from focus group discussions can be demanding. It can be extensive and time consuming. However, as seen below there are two ways of doing this analysis depending on the purpose of the research and the resources available.

### TRANSCRIBING THE TAPES

There are two ways of using the tapes from the focus group discussions depending on the human and financial resources available.

1) If the researchers are highly qualified and have enough time available then the tapes can be transcribed and analysed. They should be compared with hand written notes from the moderator and the note-taker. This is done to fill in any gaps or inaudible phrases as well as to add the flow of the discussion. Observations on whether the participants were at ease or nervous are an important addition to recorded information in order to understand the context and validity of the information. It must be noted that a full transcription of the tapes is very time-consuming and demanding.

   Sometimes the focus group discussions are carried out in a language different from that required for analysis. If it has been decided to use the tapes rather than the notes as the basis for analysis it may be necessary to translate the transcripts. It is recommended that the translator work closely with the moderators in doing the translation with occasional quality checks by the principal investigator.

2) A less resource demanding way of using the tapes is to listen to them immediately after the focus group session and compare them with the notes taken by the note-taker. The moderator and note-taker will use the tapes as back up to extend and improve on the written notes taken during the session. Themes and statements are added to the notes from the discussion and notes on emotional reactions from participants may illustrate the seriousness of a subject. The written notes will then become the basis for analysis. The advantage of this method is that it is fast and the analysis becomes much less cumbersome and time-consuming.

**IF NO TAPE RECORDER WAS USED**

If no tape recorder was used the team can use their notes and observations during focus groups and interviews in a collective approach to the analysis. The team draws up tables of analysis for each type of respondents, for instance patients (whether focus group or exit interviews) and communities in one table, another table for injection prescribers, possibly another for injection providers. The whole group fills the table together with each interviewing team reporting their conclusions for each interview conducted. The observations and data are discussed in the whole group and validated or queried in the context of the observations of the other teams.

**WHO SHOULD DO THE ANALYSIS**

It is important that the principal investigator, the moderators and the note-takers of the various focus groups participate in and discuss the analysis of the focus group data. This interaction enables the analysis to stay on track and it relates the data to the objectives of the research. It is also recommended that the principal investigator should have previous experience with the analysis of qualitative data, as this will facilitate the identification of new leads or new hypotheses.

**ANALYSIS OF THE DATA**

The analysis of the data can be conducted manually or by computer using word processing programmes such as ETHNOGRAPH ®. However, it is well to remember that the computer cannot do anything that cannot be done manually. It facilitates easy retrieval of data but computer analysis poses a risk of doing an oversimplified analysis through too early identification of marked text as key to the answers. It is crucial that the data are read carefully by the researchers to allow for identification of hidden meaning or new perspectives.

There are several complementary approaches to qualitative analysis and most or all of them should be used when analysing the focus group data. The first step is to do an initial superficial overview of the group data. The next steps are to conduct a content analysis and to develop an ethnographic summary of the data with direct quotes and narrative explanation. Deviant case analysis can provide further insights into the meaning of the data.

## Overview of group data

A simple quantification by group can give an initial but superficial impression of the concerns of various groups. It may look like this:

Example 1

Frequency of specific concerns about safety of injections mentioned by groups of patients, community members, injection prescribers and injection providers. There were four groups of each type (Table 1)

*Table 1: Specific concerns about safety of injections mentioned by groups of patients, community members, injection prescribers and injection providers*

| Concerns | Patients | Community | Prescribers | Providers | % of groups mentioning* concern |
|---|---|---|---|---|---|
| Abscesses | 4 | 4 | 4 | 4 | 100 |
| Fever | 4 | 4 | 0 | 2 | 63 |
| Hepatitis B | 1 | 2 | 3 | 1 | 44 |
| Hepatitis C | 0 | 0 | 3 | 1 | 25 |
| HIV | 3 | 4 | 4 | 3 | 88 |
| Rashes | 2 | 2 | 0 | 1 | 31 |

The table could also be filled in with patient focus groups form different areas, ages or cultural groups only. The specific tables depend on the objectives of the research. However, it is important to note that this quantification does not capture the qualitative measure of how much something was stressed, or the context in which it was discussed/mentioned. It is therefore necessary to conduct a more in-depth qualitative analysis as described below.

## Content analysis

Content analysis consists of the identification of particular themes, patterns or responses that are stated frequently by participants. The analysis looks at the number of times a theme is mentioned within a group or across all the groups and the importance and associations related to the theme. It is particularly useful to record specific reactions to themes and the context in which they were said rather than simply the themes themselves. This allows a qualitative impression of the general concerns of the groups or, in some cases, why and how they may disagree.

It is also important to note whether participants group together certain words or expressions in terms of meaning. If the participants regard Hepatitis B and C as synonymous then this indicates something about the local disease categories. Such leads to local categorization may open up new themes that can be investigated in the analysis of notes from other groups.

A. Transcript analysis with colour coding

The content analysis starts with the researchers reading through the notes or transcripts carefully. In the case of injections the researchers may be looking for perceived advantages of injections. Each of the advantages mentioned is coded in the text, for instance with colours or letters. “Quicker action” could be coded A while “when it hurts it must be powerful” could be coded B. Reasons associated with the various perceptions of advantages can be sub-coded with numbers. For instance “injections work quicker because the doctor told me so” could be coded A1 while “injections work quicker in my experience” would be A2. This enables the researchers to identify how perceptions are formed and the reasons behind them.

B. Group analysis with table for synthesis

Another way of going through this process as a group exercise is to make a table on the blackboard or white board with the vertical columns consisting of the major research themes and the horizontal columns consisting of each completed focus group or in-depth questionnaire. Each interviewing team summarizes the various conclusions for each interview and fills in the vertical column on the board. It is important that the group fills in the table with the meanings

and intentions of the respondents so that the qualitative aspects emerge. When all the completed tools have been put into the table the group will discuss the major conclusions that can be draw and the table will facilitate a synthesis of the major conclusions in a systematic way. The advantage of this method is that is stimulates collective discussion and insight in the group and it is a fast and systematic way of doing the analysis.

*Table 2: Example of analysis table*

| **Identifier** | **Respondents Location** | **Advantages injections** | **Disadvantages Injections** | **Preferred source of injections** | **Who initiates injection** | **Etc…..** |
|---|---|---|---|---|---|---|
| FG 1 | 6 women, illiterate Mazur community | Fast relief of pain and fever Cheaper because able to return to work instead of taking pills for 4 days | Some risks but not sure what, Want disposable equipment but costly, TV says disposable equipment is better | "the doctor knows best" (1 women disagreed and said doctors were motivated by greed) | Always the doctor | |
| FG 2 | 10 labourers, Patan ethnicity, illiterate Mazur community | "We always get injections so that we can go back to work" | Sometimes we get abscesses and pain and swelling at the injection site | Etc. | Etc. | |
| Exit interview 3 | Ect. | | | | | |
| FG 4 | | | | | | |

Observations on similarities of group themes or differences between groups must be summarized and discussed by the researchers. What does the data mean and how does it relate to the specific backgrounds or experiences of the participants? Does the data make sense? What are the reasons for the differences or similarities between the groups? It is important that the researchers relate the analysis to the objectives of the research and that the conclusions are relevant.

## The ethnographic summary

The ethnographic summary is developed through repeated open-minded reading of the transcripts. The researchers are not so much looking for specific themes as they are looking for underlying meaning or emergent themes. This is beyond a simple theme count and it involves the recognition of priorities or perceptions of the respondents that were not previously identified. The participants may not be answering the questions of the moderator but providing additional information that would not be picked up by a survey. Through the narrative of respondents researchers may gain insight into how people determine the efficacy of treatment or safety and sterilization. In the case of injections an emerging theme may be that of culture specific notions of sterility that differ from the biomedical view of how to sterilize. Such

emerging themes may provide valuable clues for further in-depth research and validation. When the researcher has a clear view of what the focus group respondents are trying to convey then illustrations are selected from the text and presented with narrative explanations.

## Deviant case analysis

Sometimes a specific participant may have radically different perceptions from the rest of the focus group participants. Such deviant cases may provide special insights into how perceptions are formed and sustained. If time allows an in-depth interview can be conducted with such an individual after the focus group session to understand better the reasons for the radically different perception.

### VALIDATION OF DATA

The validity of focus group data is ensured through the comparison of responses from focus groups of the same type. If for instance all of the patient and community groups mention the same risks or advantages of injections then one can be fairly certain that the information is valid. If responses are very different the data may not be valid and it should be double-checked or investigated further. The data may also be compared with data from surveys, medical records or in-depth interviews to check the validity of results. This is called triangulation of data and it means that data on the same issue but from different sources are compared.

Narratives of data can also be used to check validity of data. Although presented differently from group to group the stories may reveal similar attitudes or behaviour with regard to a certain subject. For instance, although groups may be talking about different treatment strategies, the descriptions may reveal similar perceptions of risks associated with injections.

Sometimes an emerging conclusion or theme needs to be validated through more research of the same kind or through a different kind of research method. The need for additional research should be identified at the time of analysis.

### REPORT WRITING AND RECOMMENDATIONS

Before the report is being written it is important to realize who are the main audiences for the results. Target groups may include health planners, policy makers, media, potential funding sources, medical institutions etc. Thus, the results should be linked to recommendations for action and, if needed, further research. The report should be a concise as possible and summarize the main conclusions across the various focus groups. It should highlight differences and similarities in perceptions between groups, for instance health workers' perception of safety of injections versus patients' perceptions. The report should contain examples and quotes but not attempt give all the ethnographic narratives at length. It must address the objectives of the assessment. The report should not be longer than 20- 25 pages and the conclusions must be linked to specific realistic recommendations. The main conclusions and recommendations should be presented in an executive summary.

The identified gaps in knowledge or unsafe practices must be linked to specific recommendations on the prevention messages needed and the form in which they should be delivered. Prevention or IEC messages should to the extent possible use the local terms and expressions and they should be pilot-tested before finalization. Messages should in general be positive and not start by telling people that everything they do is wrong. They should start with what people are doing right and try to build on this. For instance, if people are giving to many

injections to their children then the message could start by acknowledging that parents care deeply about their children and that they spend scarce resources on them. Then it could go on to talk about the best use of these resources stressing that injections are not the best use of these or best for their children's health.

If the radio has been highlighted by participants as influential in forming their perceptions of health and treatment then it would be natural to make use of this media. Similarly, if religious figures are important as sources of treatment advice then special efforts must be made to reach this group or to involve them in the design and delivery of prevention messages. If material or policy factors are affecting injection safety in health facilities, then workshops with relevant health officials can be considered. Health workers may get in-service training in safe injections while at the same time improving their working conditions. Informal providers may be brought together for interactive sessions with posters on injections and given supplies for appropriate sterilization. In short, there will be different messages and different ways of delivering these messages for each type of audience

**INSTRUMENT 1: GUIDE FOR FOCUS GROUP DISCUSSIONS ON INJECTIONS (PATIENTS AND COMMUNITY)**

This focus group guide is used for both patients and community members. The patient focus group consists of patients either waiting to be treated at a health facility or just leaving. The community focus group consists of members selected from households in the community (see moderator guide). It is suggested that group members in each type of focus group should be of the same sex and cultural background.

**OBJECTIVES OF THE FOCUS GROUP DISCUSSION**

(1) To explore the social and cultural meaning of injections
(2) To identify the people's perception of the therapeutic rationale behind the injections
(3) To understand the direct and indirect costs of injections
(4) To understand people's perception of injection safety.

**GENERAL INFORMATION**

Date:

Name of note-taker:

Name of moderator:

Location:

Type, sex and number of respondents:

**SUBJECTS TO EXPLORE IN SESSION**

The below listed subjects and questions may be explored in any order. If the participants have already covered a subject then there is no need to ask the specific question relating to that subject.

## What symptoms will make you seek help from a treatment provider?

- Probe for type of symptoms, perception of severity and cause.
- For which symptoms do you self-medicate?
- Are there symptoms for which you do not take any medication at all? In these cases, do you do something else?

## How and why do you choose specific treatment providers?

- Probe for which formal as well as informal providers people choose and why.
- Why this provider was chosen and what type of treatment does he normally give?
- How do you know the qualifications of a specific provider and do these qualifications matter to you?

- Who do you see for getting injections?

### How do you determine if a treatment is effective?

- Probe for efficacy in relation to injections

### Are there any specific diseases or symptoms for which injections are most effective?

- Probe for which ones and why.

### Are some providers better for providing injections than others?

- Please explain how the provider administers the injection

    - Intravenously or intramuscularly
    - Cleaning of site
    - Type of injection equipment used

- Are the reasons for people's preferences:

    - Safety
    - Convenience
    - Skills of the provider
    - Efficacy
    - Cost

### What are the reasons for the advantages of injections and IV-fluids?

- Do you prefer injections and/or IV-fluids to other types of treatment?

- How did you form that opinion?

- Probe for who educates people on health, relevant personal experiences or other local sources of health information.

### How do the direct costs (for instance provider fee) and the indirect costs (for instance cost of travel to provider) compare to the cost of other types of therapy?

- Indicate cost of prescription with injection compared to prescription without injection.

If injections are more expensive then probe for :

- Why people prefer injections, for instance perceptions of injections being a quicker cure and therefore worth more money/effort

- How often people travel for injections vs. how often they travel for other therapeutic treatment

**How do you think the injection prescribers decide on whether or not to give an injection?**

- Who initiates the injection in the therapeutic encounter, patient or provider?
- Probe for people's perception of the prescribers' therapeutic rationale.
- Do people request injections from the prescriber?
- Do these requests influence the prescriber?

**Are there any risks associated with injections or circumstances where injections should not be given? How can you avoid these risks?**

- Probe for what they are, for instance jaundice, HIV, Hepatitis B or C, abscesses
- How people know about these risks and what they do to prevent them
- What makes an injection dangerous:
  - Inadequate provider skills
  - Inadequate cleaning procedure (please describe how cleaning is done)
  - Reuse of equipment instead of using disposable syringes
  - Sharing of injection equipment among patients or family members

**Have there been times when people in this area received too many or bad injections?**

- Probe for examples, from which providers and reasons for the bad quality.

**Are there differences in men, women and children receiving injections (not immunisations)?**

- Probe for differences in prescribing patterns and perceived gender/age based reactions to injections.
- Are there circumstances (age groups or symptoms) where injections should not be given?

**Do people have their own injection equipment for use in health facilities or at home?**

If yes, probe for reasons:

- Why people have their own equipment. What type of injection equipment is it (disposable, reusable)
- Where they obtain it?

- If it is disposable syringes, how do people know that it is new? (Is it opened in front of the patients?)
- How they sterilize it if not disposable?
- Do people prefer a certain type of equipment for injections, for instance plastic or metal?
- Ask whether providers discuss people's sterilization practices with the patients
- What happens to disposable syringes after use?

### Do people get injections outside health facilities? If yes, where and why does this happen?

Probe for:

- Who gets these injections?
- Who administers them (Relative, dispensary, traditional healer, hospital, other)?
- What are the conditions?
- Why this treatment or provider is chosen?

### What do you think happens to syringes and needles after they have been used and discarded?

- Do you see used syringes lying around on tables and floors of health facilities?
- Can they be found in your environment?
- Do they lead to needle stick?
- Are needle sticks risky and why?

### Do you have any suggestions for how injection practices can be improved in your community?

- Probe for credible sources of future health information (providers, teachers, religious figures etc.)

**INSTRUMENT 2: GUIDE FOR FOCUS GROUP DISCUSSIONS ON INJECTIONS (INJECTION PRESCRIBERS)**

This focus group consists of the health workers, midwives, nurses and doctors who prescribe the injections. They may not always be the ones who actually administer the injections to patients. In some cases it may not be possible to do focus group discussions with private doctors or providers. In these cases the present focus group guide can be used as a guide for an in-depth interview with the prescriber instead.

**OBJECTIVES OF THE FOCUS GROUP DISCUSSION**

(1) To understand prescribers' therapeutic rational and other motives for prescribing injections
(2) To explore the prescribers' understanding of overuse and safety issues relating to injections
(3) To understand how the working environment of the prescriber may impact on the prescription and safety of administered injections

**GENERAL INFORMATION**

Date:

Name of note-taker:

Name of moderator:

Location:

Type, sex and number of respondents:

**SUBJECTS TO EXPLORE IN DISCUSSION**

The below listed subjects and questions may be explored in any order. If the participants have already covered a subject then there is no need to ask the specific question relating to that subject. One subject that may deserve additional attention is safety of injections. Focus group moderators may wish to develop an additional data collection instrument on safety issues in order to identify underlying reasons for lack of safety in injection administration. This should be decided after the data on safety from the focus groups have been analysed and discussed.

## Where were you trained and how long have you been practising medicine?

The purpose of these questions is to identify whether this prescriber is medically qualified or not.

- Training institution if any
- Practising in general
- Practising in this area

## What are the main diseases in the area?

- How often do you see patients with Hepatitis B or C?

- What advice (prevention, care) do you give them?
- How do you treat them?

### How many patients do you treat per day? How many of these receive an injection? How many receive IV-fluids?

### Are there any specific diseases, symptoms or situations for which injections (other than immunisations) and IV-fluids are most needed?

Injections, probe for:

- Which ones?
- What makes injections needed in these situations?
- Which ones do not require injections?

IV-fluid, probe for:

- Which ones?
- What makes IV-fluid needed in these situations?

### What are the advantages and disadvantages of injections and how do providers form this opinion?

Probe for:

- Sources of therapeutic knowledge
- Perceptions of efficacy
- Patient compliance etc.

### What is the cost of a prescription with and without injections?

- With injection:
- Without injection:

### What is the cost of IV-fluid?

### What types of injectables and IV-fluid do you use most often?

- List the injectables and IV-fluids mentioned and the indications for which they are use.

## Are there any risks associated with injections?

Probe for knowledge of:

- Hepatitis B
- Hepatitis C
- HIV transmission
- Allergic reactions
- How do prescribers get this type of knowledge?

## Are there factors in your health facility that promote or constrain the prescription of injections? How can rational prescribing of injections be promoted?

- Are there any differences between your government and your private practice in this respect? (This question is only relevant for providers with both public and private practice).
- The below listed probes are particularly relevant for government prescribers where supplies may be a major issue. Probe for the impact of
    - Resources
    - Medical supplies
    - Injection equipment supplies
    - Health system structures
    - Policies/treatment guidelines
    - Patients resources

## Do patients demand injections?

- Why do you think patients demand injections?
- Are there specific situations or symptoms that normally lead patients do demand injections?
- Are there differences between patients in this respect? (Probe for socio-economic groups, age, and sex).

## Is the interaction with a patient different if you are prescribing an injection rather than other types of medication?

Probe for:

- The amount of time spent with patient
- Dialogue
- Cost of visit with and without injection

- Do patients come in demanding injections for themselves? For children?
- How do you handle that?

### Does the prescription of injections have an effect on the status, income or popularity of prescribers among patients or colleagues?

Probe for how it affects relations with:

- Colleagues
- Incentives
- Why they think patients want injections

### Are there differences in injection prescribing patters for women, men, children (not counting immunisations) or the elderly?

- Probe for type of differences and reasons

### Do people in this community/area receive too many or bad quality injections?

- Probe for examples and sources of bad injections as well as explanations
- How do you sterilize your injection equipment? Please explain the procedures.
  Probe for factors affecting safety such as:
    - Reuse of syringes and needles
    - Resources
    - Personnel
    - Sufficient supplies of syringes, needles, sterilization equipment and materials
    - Structures and policies
    - Time constraints
    - Lack of knowledge
    - Supervision etc

### Do people have their own injection equipment for use in health facilities or at home?

If yes, probe for:

- Why people have their own equipment?
- What type of equipment is it (disposable, reusable)?
- Where do they obtain it?
- How do they sterilize it?
- Ask whether providers discuss people's sterilization practices with the patients

**Do people get injections outside health facilities and home? If yes, where and why does this happen?**

Probe for:

- Who gets these injections
- Who administers them
- What are the conditions
- Why this treatment or provider is chosen

**What happens to syringes and needles after they have been used and discarded?**

Probe for:

- If and how and where they are disposed off
- Whether there are any risks for health workers or community
- Suggestions for improvements

**Do you have any suggestions for improving injection practices in this area?**

**INSTRUMENT 3: GUIDE FOR FOCUS GROUP DISCUSSIONS ON INJECTIONS (INJECTION PROVIDERS)**

This focus group will consist of the people who actually administer the injections. In some health facilities these may be lower level health workers or even other types of employees associated with the health facility (e.g. janitors). If it turns out that the injection prescriber also administers the injections, there is no need to interview the dispenser.

In other settings it may be informal providers such as pharmacy or shop assistants or traditional healers who give injections as part of their business/practice. Preliminary investigation should identify who the local injection providers are so that all types can be represented in the relevant focus group. The objectives of this guide are to understand the providers' perception of safety issues in connection with administering injections.

**OBJECTIVES OF THE FOCUS GROUP DISCUSSION**

(1) To explore the providers' understanding of injection safety issues.
(2) To understand how the working environment of the provider may impact on the safety of administered injections.

**GENERAL INFORMATION**

Date:

Name of note-taker:

Name of moderator:

Location:

Type, sex and number of respondents:

**SUBJECTS TO EXPLORE IN THE DISCUSSION**

The below listed subjects and questions may be explored in any order. If the participants have already covered a subject then there is no need to ask the specific question relating to that subject. One subject that may deserve additional attention is safety of injections. Focus group moderators may wish to develop an additional data collection instrument on safety issues in order to identify underlying reasons for lack of safety in injection administration. This should be decided after the data on safety from the focus groups have been analysed and discussed.

## Where were you trained and how long have you been working in his field?

The purpose of these questions is to identify whether this dispenser is qualified or not:

- Training institution if any
- Training in general
- Practising in this area

**How many patients do you dispense medicines to per day? How many of these receive an injection? How many receive IV-fluids?**

**Are there any specific diseases or symptoms for which injections are most effective?**

- List each of the diseases/symptoms for which injections are most effective.
- Why are injections most effective for these conditions?

**Are there any specific diseases or symptoms for which IV-fluids or blood products are most effective?**

- List each of the diseases/symptoms for which IV-fluids or blood products are most effective.
- Why are IV-fluids or blood products most effective for these conditions?

**What is the cost of a prescription with and without injections?**

- With injection:
- Without injection:

**What is the cost of IV-fluid?**

**Are patients able to pay the doctor's fee?**

- Are the credit possibilities?
- Can poor people be exempted from paying?

**What types of injectables and IV-fluid do you inject most often?**

- List the injectables and IV-fluids mentioned and the indications for which they are used.

**What are the advantages and disadvantages of injections for patients and providers and how do providers form this opinion?**

Probe for:

- Sources of therapeutic knowledge
- Perceptions of efficacy
- Patient reactions etc

### Are there any risks associated with injections?

- What viruses are most easily transmitted through unsafe injections?
- What about hepatitis B?
- What about hepatitis C?
- What about HIV
- What about abscesses?
- What about needle stick injuries?
- How did you find out about risks associated with any of the above conditions?

### What types of syringes are normally used to administer injections?

- Disposable syringes, new or used
- Reusable syringes with new needles
- Auto-disable

### Please explain what makes an injection safe or unsafe.

Probe for which procedures precautions should be employed to administer a safe injection:

- Washing hands
- Clean preparation surface
- Sterile needle and syringe
- Safe handling of multi-dose vials
- Skin disinfecting
- Sterilisation of needles and syringes
- Storage of needles and syringes
- How feasible are the above procedures in your setting?

### If syringes and or needles are reused between patients in your setting/facility, please explain how they are sterilized and stored for later use.

Probe for:

- Adequate procedures,

- Equipment
- Materials and
- Knowledge

### Is safety of injection administration a problem in your setting/facility?

Probe for factors affecting safety such as:

- Resources
- Personnel
- Sufficient supplies of syringes, needles, sterilization equipment and materials
- Policies and guidelines
- Time constraints
- Lack of knowledge
- Supervision etc

### How are syringes and needles collected in the treatment room after they have been used and what happens to them afterwards?

Probe for:

- If, how and where they are disposed off?
- Whether there are any risks for providers or community?
- Whether there are needle stick injuries in the specific setting/facility?
- Who is affected by it?
- Why do people get these injuries?
- Suggestions for improvements.

### Do people have their own injection equipment for use in your setting, in health facilities or at home?

If yes, probe for reasons:

- Why people have their own equipment
- Where they obtain it and

- How they sterilize it. Ask whether providers discuss people's sterilization practices with the patients

**Do people in this community/area receive too many injections?**

- Please give some examples
- Where do people go for their injections?
- Why do they go there?
- Why do people receive too many injections?

## Do people in this community/area receive bad quality injections?

- Please give some examples
- How do you know that it is a bad quality injection?
- Why do people get bad quality injections?
- Who administers such bad quality injections?
- Why do they do so?

**INSTRUMENT 4: GUIDE FOR FOCUS GROUP DISCUSSIONS ON INJECTIONS (AUXILIARY STAFF / WORKERS HANDLING HEALTHCARE WASTE)**

This short focus group will consist of the people handle healthcare waste, including used injection equipment. In some health facilities these may be lower level health workers or even other types of employees associated with the health facility (e.g. janitors).

**OBJECTIVES OF THE FOCUS GROUP DISCUSSION**

The objectives of the focus group sessions with auxiliary workers / workers handling medical waste are:

1) To understand the staff perception of the risks related to accidental needlestick injuries;

2) To understand the reasons why healthcare waste is not disposed of adequately;

3) To understand which risk may occur in the community.

**SUBJECTS TO EXPLORE IN THE DISCUSSION**

The below listed subjects and questions may be explored in any order. If the participants have already covered a subject then there is no need to ask the specific question relating to that subject.

## How are syringes and needles collected from the healthcare facility and what happens with them afterwards?

Probe for:

- Do needlestick injuries occur when people are handling waste?
- Why do needlestick injuries occur?
- Do needlestick injuries cause illnesses?
- Where is the storage are located?
- Who has access to the storage area?

## How does the waste get disposed of?

Probe for:

- Have you ever been injured while operating the waste disposal facility?
- What do you do when the disposal facility does not function, or when the waste is not collected?
- Is the waste treated in an adequate way? If not, why?
- Do you think the community is at risk from needlestick injuries because of the waste?

## INSTRUMENT 5: EXIT INTERVIEW FOR PATIENTS

If it is difficult to conduct focus group discussions with patients in the waiting rooms of private doctors, then an exit interview can be chosen instead. An exit interview means that an interviewer interviews a number of patients, one at a time, as they leave the health care facility. It is important to do so out of sight of the doctor or provider so those patients can speak freely. Certain criteria can be employed in selecting patients for exit interview, for instance every third patient should be interviewed or a certain number of men and a certain number of women should be interviewed.

The research advantage of an exit interview is that the interviewer can ask questions about the therapeutic interaction that just took place. This enables the patient to give very concrete answers in additions to the general opinions. This may facilitate contact and insights into common injection practices.

Exit interviews can provide an easy way of collecting baseline information before interventions. They can be repeated at regular intervals to measure changes in the number of patients who receive an injection or IV fluid (or other relevant indicators).

### GENERAL INFORMATION

Date:

Name of note-taker:

Name of moderator:

Location:

Type of respondent:

### SOCIO-ECONOMIC INFORMATION

- What is your age?
- Gender and ethnicity if possible:
- Did you ever go to school and to what grade?
- What work do you do?
- What brought you to a doctor?

**TREATMENT JUST RECEIVED**

**Do you know about the qualifications of the doctor? If yes, how did you obtain this information? Is this important for you?**

**What treatment did the doctor prescribe?**

- Ask about the treatment procedures that he/she has experienced in the facility

**What was the total cost of the treatment?**

- Probe: cost of medicine, doctor, time cost, distance covered and time spent

**If injection is mentioned as part of the treatment then ask about the cost of the injection.**

**If injection is not mentioned or was not given in the just received treatment, then ask that whether injections have been received before:**

- Who suggested for injection? (Doctor/himself or herself)
- Probe: Why
- Who gave you the injection?
- Where did the syringes come from and what type was it?
- Was the syringe new or used? Was it opened in front of you?
- Is cleaning of the syringes equipment is required? How does this normally take place?
- Are you satisfied with the injection procedure?
- How the dispenser administered the injection?

- Intravenously
- Intramuscularly
- Cleaning of site of injection

- In your opinion how should the syringes be cleaned?
- Did you see used syringes lying around in the clinic?
- Probe: on floor, tables, in waste-basket etc

**QUALITY OF TREATMENT**

### Are you satisfied with the treatment?

- Probe: Why or why not?

### What in your opinion is good quality treatment?

- Probe: What should be included and excluded in the treatment?

**OPINION ABOUT DRIPS / BLOOD PRODUCTS / INJECTION**

### What is your opinion about giving injections for treatment?

- Probe: Why do you have this opinion?

### Can you name the diseases/conditions for which injections should be given?

- Probe: Why

### What is your opinion about giving drips for treatment?

- Probe: Why/how

### Have you ever been given/taken any drip?

- Probe: For what conditions and why?

### In what conditions should drips be given to patients?

- Probe: Why?

**HAZARDS AND BENEFITS OF INJECTIONS**

### Are there any hazards or benefits of injections?

- Probe: What / Why for each hazard and benefit.
- For abscesses and pain etc
- How can you avoid these?

### Are there any hazards and benefits of IV-fluids?

- Probe: What / Why for each hazard and benefit.

- How can you avoid these?

### Are there any hazards and benefits of taking blood?

- Probe: What/why for each hazard and benefit.
- How can you avoid these?

### Have you heard about hepatitis before?

- Probe: If yes, what do you know about it and where did you get the information?

**SOURCE OF INFORMATION**

### From where do you get information on health care?

### Where do you get most of the information about injection use and its benefits and hazards?

**FACILITY INFORMATION**

### Why do people come for treatment to this facility compared to elsewhere?

- Probe: advantages and disadvantages/cost/ reason of preference

### Do they go anywhere else?

- Probe: Why and when?

**SUGGESTIONS FOR IMPROVEMENT**

### Do you have general suggestion for improvement in the quality of treatment/health care in your community?

### Do you have any suggestions for improvement for injection use?

- Probe: when should injections be used or when not?
- How should used syringes be cleaned? Please explain the cleaning procedures.

### Ask whether the patient has any questions regarding anything

WORLD HEALTH ORGANIZATION (WHO)

BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL II (BASICS II)

SAFE INJECTION GLOBAL NETWORK (SIGN)

# TOOL "B" TO ESTIMATE THE FREQUENCY OF INJECTIONS AND IDENTIFY INJECTION PROVIDERS

THIS DOCUMENTS IS PART OF A TOOLBOX TO ASSESS AND EVALUATE INJECTION PRACTICES. THE COMPLETE TOOLBOX INCLUDE THE RAPID ASSESSMENT AND RESPONSE GUIDE AND FOUR ADDITIONAL TOOLS (A, B, C, AND D)

This toolbox addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS, Arlington, VA, USA in March 2000. It constitutes a dated draft circulated for comments and suggestions. Although it is made widely available at an early stage, it is not yet intended to be a "how-to" manual for field use. Later versions of this document will be adapted for wider readership level once consensus has been reached on broad concepts and after field testing.

Comments and suggestions should be directed to the Secretariat of the Safe Injection Global Network (SIGN), World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, Geneva 27, Switzerland 1211. Fax +41 22 791 4836. E-mail: sign@who.ch.

| **Intended use and proposed timeline for this document** | |
|---|---|
| Preparation of draft 1 by selected consultants | February 22, 2000 |
| Review of the draft 1 by a group of experts and preparation of draft 2 | April 30th, 2000 |
| Review of draft 2 by workshop participants to prepare draft 3 | May 31st, 2000 |
| Field testing of draft 3 in few countries to prepare draft 4 | September 1st, 2000 |
| Wider dissemination of draft 4 for broad use and ongoing feedback | 2000-2002 |
| Preparation of a final version after two years of feedback from the field | End of 2002 |

## B- TOOL TO ESTIMATE THE FREQUENCY OF INJECTIONS AND IDENTIFY INJECTION PROVIDERS

### INTRODUCTION

To better direct safe and appropriate use of injection activities, the managers of an injection safety initiative need to:

1) Estimate the frequency of injection in the population;

2) Identify the providers who administer injections to the population.

This tool proposes an approach to estimate injection frequency and identify injection providers.

### BACKGROUND

#### POTENTIAL METHODS TO ESTIMATE THE FREQUENCY OF INJECTIONS

The following information sources may be used to obtain information on injection frequency:

### Population studies

These include:

- Population-based injection frequency survey;
- Reference group of analytical studies studying the association between injections and infections (e.g., the control group of a case-control study investigating the association between injections and hepatitis B virus infection [1] provides information regarding the frequency of injection in the population);
- Studies estimating the frequency of injections given for selected purposes (e.g., immunization, contraceptive, injection drug use, and insulin).

Compared to other information sources, only population studies can provide an estimate the number of injections administered by informal injection providers and traditional healthcare providers.

### Healthcare use indicators

Estimates for the frequency of injection use in the population can be obtained on the basis of:

- The proportion of prescriptions including at least one injection (See the WHO/ EDM OT8 indicator in the rapid assessment and response guide);
- The annual number of outpatient visits per capita (Available from the World Bank [2])

## Market analysis indicators

These include:

- Indicators used in marketing studies performed by private consulting firms (e.g., number of disposable syringes sold in one country);
- Manufacturers' sales data.

### POTENTIAL METHODS TO IDENTIFY INJECTION PROVIDERS

While population studies, healthcare use indicators, and market analysis indicators can all provide information that can be used to estimate the frequency of injections in the population, only population surveys can determine how injections received by the population are distributed according to various injection providers.

### PROPOSED OPULATION SURVEY METHODS

### RATIONALE OF THE APPRAOCH

Population surveys constitute a method of choice during an initial assessment of injection practices as they allow both estimating injection use in the population and identifying injection providers. To make the best use of human, material, and financial resources needed for population surveys, care should be taken to:

1) Include the data collection instrument proposed in this tool to other population surveys that may be conducted for other purposes (See "Integration with survey conducted for other purposes", Page 4);
2) Study the relationship between injection frequency (a) as measured through population studies and (b) as measured through healthcare use indicators (i.e., the WHO/DAP OT8 indicator), so that monitoring changes of the OT8 indicator can allow estimating the change in the frequency of injection use in the whole population.

In the absence of resources to conduct a population survey, healthcare use indicators provide rapid estimate of injection frequency in the population.

### OBJECTIVES

The objectives of an injection use survey are to:

1) Estimate the frequency of injection in the population;
2) Determine how injections received by the population are distributed according to various injection providers.

**METHODS**

## Study design

Cross sectional population survey.

## Integration with survey conducted for other purposes

Planned population surveys (e.g., Multi-Indicator Cluster Surveys [MICS], Demographics and Health Surveys [DHS], community IMCI) should be identified with the objective of adding items regarding injection use to the questionnaire.

## Study population

The general population for which injection safety activities are planned or being conducted. Depending on the setting, this general population may be the whole country, a province, or a pilot district.

## Study sample

Sampling unit
The proposed sampling unit is an individual person. (To allow comparison across settings where household sizes and age structure may differ, collection of information at the individual level is preferred to collection of information at the household level.) [3,4,5]

Sampling frame
Ideally, the study sample should be a sample representative of the study population. If resources do not allow taking a sample of the general population, a sample of a selected subgroup thought to be representative of the general population may be selected as a surrogate (e.g., one province or one district may represent a country if thought generally representative).

Stratifications
Decision should be made regarding plans to conduct comparisons between two different population subgroups (e.g., rural versus urban) or plans for before / after comparisons.

Sampling methods
Any valid method to obtain a structured, representative sample of the general population is acceptable. An option that is both simple and adapted to developing country settings is the use a cluster sample derived from the methodology used for EPI coverage surveys [6]. Calculation of the design effect will take into account the clustering of injection practices among households.

Sample size
The sample size should be calculated on the basis of:

1) The expected proportion of the study sample reporting an injection during the referent exposure period (i.e., the last three months);

2) The desired +/- percentage point precision around the best estimate;

3) The desired confidence interval;

4) The expected design effect if a cluster sample is to be used.

If comparisons between two different population subgroups (e.g., rural versus urban) is needed or if before / after comparisons are planned, the sample size should be multiplied by two.

Table 1 proposes a number of potential samples sizes that should be multiplied by the expected design effect in the case of a cluster sample. For example, based upon a 40% expected proportion of the population having received an injection, for a +/- 5 percentage point precision around the best estimate, and for a 95% confidence interval, 369 subjects are needed in case of simple random sampling (shaded grey, Table 1). In case of a cluster sample with an expected design effect of 2, the number of subject needed will be 738 (369 x 2). The number of households to include can be calculated by dividing the sample size by the mean household size obtained from census data.

*Table 1: Potential sample sizes for the population surveys, for a 95% confidence interval* [*].

| Desired precision around the best estimate of the proportion (In percentage points) | Expected proportion of the population having received an injection in the last 3 months [†] | | | | |
|---|---|---|---|---|---|
| | 10% | 20% | 30% | 40% | 50% |
| 2% | 864 | 1,534 | 2,013 | 2,300 | 2,395 |
| 5% | 138 | 246 | 323 | 369 | 384 |
| 10% | 35 | 61 | 81 | 92 | 96 |

## Definition of an injection

A procedure which pierces the skin or a mucosal membrane to introduce a substance into the body. This case definition should be adapted according to the concept of an injection in the local language.

## Human subjects

Because this tool is designed to evaluate routine use of injection in the population, it should not be considered as research and thus is not subject to an Institutional Review. Board (IRB) approval. However, institutions taking responsibility for this field assessment should check locally to determine whether any ethical counsel or approval is needed or not before conducting the survey.

[*] Sample size shown should be multiplied by the expected design effect (e.g., 2) if a cluster survey design is to be used.

[†] Proportion of the population having received an injection during the referent period (i.e., the last three months).

## Data collection procedure

Interviews of study subjects

Information should be collected during face-to-face interviews conducted during household visits. Persons 15 years of age or older should reply to the questions directly while adult caretakers should be respondents for children under the age of 15.

Information to be collected

*Minimum set of information*

Using standardized questionnaires, information should be collected from each study participant regarding:

1) Demographic characteristics (age, sex);

2) Number of injections or intravenous infusions* received during a three months referent period. † To facilitate recall and limit the risk of underreporting of injections, different injection providers may be mentioned to the study participant;

3) The provider who administered the last injection received. Proposed options to answer this question should be adapted to the identified injection providers and the names used by the population to identify them‡).

*Additional information that may be collected if time and resources allow*

If time and resources allow (e.g., if the survey is being conducted as a stand alone study), additional information may be collected during a population survey, including:

1) The proportion of injections received that were given for the purpose of a vaccination;

2) The setting where the injection was administered (e.g., home, outpatient clinic, hospital, dental office);

3) The safety circumstances of the last injection received as reported by study participants (e.g., whether injection equipment came out of a sterile package, was fitted with two caps, came from a pot of tepid water, or whether the study participants cannot remember);

4) The price paid for the last injection.

5) The number of accidental needlestick injuries from inadequately disposed sharps waste in the last 12 months.

Population survey sample questionnaires are proposed in the "Sample questionnaire for the injection frequency population survey" [Instrument 1], Page10). These templates

* The definition of an injection and of an intravenous injection should be adapted to the local language and understanding of the population.

† Longer referent exposure period may be unreliable.

‡ Identification of injection providers and the names used by the population to identify them is one of the objectives of the contextual assessment.

may need adaptation according to the local setting or the recent circumstances (e.g., If a recent mass immunization campaign was conducted, the questionnaire may be modified to include items that would capture injections given during the mass campaign).

*Additional level of sophistication*

If an additional level of sophistication is possible in a stand-alone survey, more detailed information may be collected according to the matrix proposed on Table 2.

*Table 2: Proposed information collection matrix for a stand-alone population survey to estimate injection frequency and identify injection providers.*

| **Provider** * | **Setting** | **Number of injections received in the last 3 months** | **Chief complaint** | **Medication (If possible)** | **Total cost** | **Did the syringe come from a newly opened package?** |
|---|---|---|---|---|---|---|
| Nurse | | | | | | |
| Informal injection provider | | | | | | |
| Physician | | | | | | |
| Family member | | | | | | |
| Traditional healthcare provider | | | | | | |
| Other | | | | | | |

## Limitations

Estimation of the frequency of injections may be underestimated by surveys conducted using this methodology because of a recall bias. Thus, estimates provided by population surveys could be compared to estimated obtained from other data sources if they are available.

## Data analysis

Data analysis should aim at the calculation of the following key indicators:

Question A

- The proportion of the population who received an injection in the lest three months (Question A)

- The average number of injections per capita and per year
  (based upon the average number of injections per capita for 3 months, and multiplied by 4)

Question B

- The ratio of immunization versus curative injections

Question D

- The distribution of injection providers for the last injection received

Question E

- The distribution of settings for the last injection received

Question F

- The proportion of injection given with a syringe coming from a blister package or fitted with two caps among the last injections received

* Name and contact information could also be collected in this column.

Question G

- The average price paid for the last injection.

Question H

- The annual incidence of accidental needlestick injuries with needles left in the environment.

**INSTRUMENT 1: SAMPLE QUESTIONNAIRE FOR THE INJECTION FREQUENCY POPULATION SURVEY**

**SUGGESTED WORD OF INTRODUCTION** [*]

*[Greetings] My name is _____, and I work with [Institution]. [Institution] is doing a survey about injections and health care. To do this survey, we are asking questions about injections you may have received in the recent past. You have been chosen at random to take part in this survey. The questions will take less than 5 minutes to complete. Taking part is your choice. If you feel you do not want to answer some of the questions, you can choose not to answer any of the questions or tell us to stop at any time, without any consequence for you. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.*

Cluster: ____ Family: ___ ID code within family: ____

Age: ____ years Sex: 1- Male 2- Female

**A. During the last three months, that is between <date> and <date> †, did you receive an injection or an IV infusion?**
**Prompt: The potential persons who may have given you an injection or an IV infusion include your doctor, your nurse, your dentist, a relative, any other person or caregiver, or yourself)**

1 - Yes If yes, how many? _____ 2- No

**B. (If yes to question A) How many of these injections were given by a health care worker for the purpose of a VACCINATION?**

How many? _____

**C. Can you remember the last injection you have received?**

1 – Yes 2 - No 3- Don't know

**D. (If yes to question C) Can you remember who gave you this last injection?**

1 – A medical doctor 2- A nurse 3- A dentist 4- A traditional healer
5- Someone else 6- Me, myself 7- I don't remember

**E. (If yes to question C) Can you remember where you received this last injection?**

1- Outpatient clinic 2- Hospital 3- Dental office 4- Home 5- Don't know

**F. (If yes to question C) Can you remember where the needle and the syringe that were used to give you this last injection came from?**

1 – It came from a blister package 2- It was fitted with two caps 3- It came from a pot of tepid water ‡
4- It came from a sterilizer 5- Other (specify) _____ 6- I don't know/ remember

**G. (If yes to question C) Can you remember what you paid for this injection? ____ Total**

____ For the medication ____ For the syringe / needle ___ For the injection service fee

[*] This note should be adapted to each country and may be subject to ethical committee review or approval.

[†] Adjust dates to a three-month time period, using local calendar events if necessary.

[‡] This may need to be modified according to the local practices when re-using syringes and needles without sterilisation.

**H. During the last year, that is between <date> and <date> *, where you accidentally stuck by a injection needle that was left in the garbage or in the environment:**

1 – Yes Number of times 2 - No 3- Don't remember

____

* Adjust dates to a 12-month time period, using local calendar events if necessary.

## REFERENCES


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WORLD HEALTH ORGANIZATION (WHO)

BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL II (BASICS II)

SAFE INJECTION GLOBAL NETWORK (SIGN)

# TOOL "C" FOR THE ASSESSMENT OF INJECTION SAFETY

THIS DOCUMENTS IS PART OF A TOOLBOX TO ASSESS AND EVALUATE INJECTION PRACTICES. THE COMPLETE TOOLBOX INCLUDE THE RAPID ASSESSMENT AND RESPONSE GUIDE AND FOUR ADDITIONAL TOOLS (A, B, C, AND D)

This toolbox addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS, Arlington, VA, USA in March 2000. It constitutes a dated draft circulated for comments and suggestions. Although it is made widely available at an early stage, it is not yet intended to be a "how-to" manual for field use. Later versions of this document will be adapted for wider readership level once consensus has been reached on broad concepts and after field testing.

Comments and suggestions should be directed to the Secretariat of the Safe Injection Global Network (SIGN),
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| **Intended use and proposed timeline for this document** | |
|---|---|
| Preparation of draft 1 by selected consultants | February 22, 2000 |
| Review of the draft 1 by a group of experts and preparation of draft 2 | April 30th, 2000 |
| Review of draft 2 by workshop participants to prepare draft 3 | May 31st, 2000 |
| Field testing of draft 3 in few countries to prepare draft 4 | September 1st, 2000 |
| Wider dissemination of draft 4 for broad use and ongoing feedback | 2000-2002 |
| Preparation of a final version after two years of feedback from the field | End of 2002 |

## C- TOOL TO ASSESS INJECTION SAFETY

### INTRODUCTION

Injection safety should be assessed using standardized methods to allow comparison across countries. These methods should be also simple and flexible. This tool proposes a standardized methodology including concepts, study designs, sampling procedure, data collection, data analysis, and reporting for the assessment of injection safety in healthcare facilities. It updates the structured observation tool that was proposed by the WHO Drug Action Programme (DAP) [1] and the various injection safety tools that have been developed in the context of the Expanded Programme on Immunisation (EPI).

### THE VARIOUS LEVELS OF THE SAFE INJECTION DEFINITION

There are three levels for the definition for a safe injection. The first level is an ideal, reference definition. The second level represents international best practices that are a translation of the reference definition into an explicit list of critical steps for which best practices are recommended on the basis of (a) best available evidence or (b) expert consensus in the absence of evidence. The third level is the adaptation of international best practices into a national standard that takes into account operational constraints in the field.

### REFERENCE DEFINITION OF A SAFE INJECTION

A safe injection does not harm the recipient, does not expose the provider to any avoidable risk, and does not result in any waste that is dangerous for other people. This reference definition is ideal but it cannot be used as a checklist of practices for assessment or evaluation.

### BEST INJECTION SAFETY PRACTICES

The reference definition of a safe injection can be transferred into a list of critical step for which best practices should be followed. For example:

- In order not to harm the patient, the injection should be administered with a sterile syringe and needle, using the right medication etc…
- In order not to expose the provider to any avoidable risk, the needle should be placed in a puncture proof container immediately after use;
- In order not to result in any waste that is dangerous for other people, shapers waste should be discarded appropriately.

The formulation of international best practices is in progress and should be available by the end of year 2000.

### NATIONAL STANDARDS

At country level, the best practices document should be adapted into national standards developed through a participatory approach that involves all stakeholders (e.g., those who administer injections, those who prescribe them, those who are in charge of the logistics etc.). Guidelines to develop country-level standards have been proposed. [2]

## REQUIREMENTS OF AN INJECTION SAFETY ASSESSMENT TOOL

This injection safety assessment tool was designed to determine how injections given in a facility, a district, or a country depart from the national standard. It is attempting to meet the following three requirements:

### SIMPLICITY

An injection safety assessment tool need to be simple, so that persons at district level can conduct an assessment rapidly and with limited resources. Although this tool is still complex in terms of number of questions and time needed for administration, it was fully structured for ease of use and standardized administration. Thus, it should require minimal training when used by someone familiar with injection safety.

### STANDARDIZATION

An injection safety assessment tool should include a core set of items that constitute a checklist based upon the critical steps that make an injection safe or unsafe.

### FLEXIBILITY

An injection safety assessment tool should be flexible so that assessment could be conducted under various circumstances:

1) Need of an assessment at country, district, facility, or health post level;

2) Need of an assessment of the private, public, informal, or traditional sector;

3) Need of various levels of accuracy and precision, requiring various sampling and sample size schemes (E.g., structured, convenience, or key informant assessment);

4) Availability of various human, material, and financial resources.

## OBJECTIVES

The objectives of an injection safety assessment are:

1) To determine whether a facility where injections are given meets necessary requirements for staff competence, equipment, supplies, and waste disposal;

2) To determine whether the critical steps of an injection administration are executed according to recommended best practices;

3) To identify the unsafe practices that may lead to infections and that should be targeted by injection safety interventions;

4) To estimate the proportion of healthcare facilities where injection practices are safe.

## STUDY DESIGN

### TYPE OF STUDY

Cross sectional, observational study.

### INTEGRATION TO FACILITY SURVEYS CONDUCTED FOR OTHER PURPOSES

#### IMCI facility surveys

Background
In the context of the IMCI, healthcare facilities surveys may be conducted to assess the management of sick children.

Information collected of potential interest to injection safety
During the IMCI healthcare facility surveys information are collected regarding issues that are relevant to injection safety, including sources of clean water, availability of syringes and needles for vaccination, presence of a functional sterilizer, and the presence of a fridge.

Potential for integrated surveys
If IMCI healthcare facility surveys are planned, arrangements may be made to join forces and conduct a simultaneous injection safety assessment.

#### WHO/UNAIDS/MEASURE facility surveys

The WHO/UNAIDS/MEASURE project to define standardized evaluation packages to evaluate HIV/AIDS prevention activities will contain a facility assessment package to which the injection safety assessment tool may be integrated.

### SETTINGS

#### Type of injection providers

Various providers may give injections. The additional SIGN Tool B to estimate the frequency of injection according to injection providers aims at identifying the providers who administer injections. Depending on the distribution of the injections received by the population according to various injection providers, information on injection safety may be needed regarding several types of providers (e.g., primary care, lay healthcare workers, outreach facilities etc…). This tool was primarily designed to assess the safety of injection administered by injection providers in primary healthcare facilities. If injection practices of other providers need to be assessed, this tool may be used. However, the proposed sampling may require adaptation as a sampling frame may not be available for other injection providers.

#### Type of facilities

The data collection instrument proposed in this tool is designed for application in primary care settings, dispensaries, and other facilities where injections constitute the majority of skin-piercing procedures.

For other settings where many other skin piercing procedures are conducted, including hospital and dental offices, the present injection safety assessment tool may be too limited in its scope to identify the infection control practices that may lead to the transmission of infections. Additional tool will be developed in the future to evaluate infection control procedures for all skin piercing procedures in these facilities.

### SAMPLING PROCEDURE

Sampling should be done a few weeks before the planned date for the survey to allow sufficient time to schedule travel and relevant administrative authorizations.

### PRINCIPLE

The sampling unit will be the healthcare facility. To minimize in-country travel, a two-stage, cluster-sampling method is proposed as the easiest method to obtain a representative sample of healthcare facilities. [3] In such a cluster sampling, self-weighing in ensured through 1) choice of regions in which clusters are selected using probability proportional to size and 2) equal number of sampling units within each cluster.

## First stage

Division of the country in regions

First the country should be divided in regions (e.g., districts) that should be 1) non-overlapping (i.e., no village should be located in two regions) and 2) mutually exhaustive (i.e., the sum of the regions should be equal to the country). The level of regions (e.g., province, district, etc…) should be chosen so that 1) the number of region exceeds 8 and 2) each region contain at least 10 primary healthcare facilities. In case it is not possible to find regions with at least 10 primary healthcare facilities, adjacent regions may be merged to form regions containing a sufficient number of primary healthcare facilities.

Note: If a number of regions cannot be visited for any reason (e.g., civil unrest), they should be excluded from the list of regions at this stage.

Choice of regions with a probability proportional to the population size

Among these regions, eight geographic regions will be selected with a probability proportional to the total population size. To proceed to this selection, the following six steps should be followed:

*Step 1: Ranking of the regions on a table*

All regions should be displayed on the first column of a table, in whatever order is most convenient (See example on Table 1).

*Step 2: Calculation of the population size for each region*

The population size should be obtained for each region and written on the second column, next to the region name (Example: 30,000 for region 10, Table 1). Census data, even outdated, or the best available equivalent should be used.

*Step 3: Calculation of the cumulated population size*

The cumulated population size should be obtained for each region and written on the column next to the population size, on column 3. For region 1, the cumulated population size is the population of region 1. For region 2, the cumulated population size is the population of region 1 + population of region 2. For region n, the cumulated population size is the population of region 1 + population of region 2 + (…) + population of region n. Example: 565,000 for region 10

(Table 1). For the last region, the cumulated population size is the population of region 1 + population of region 2 + (…) + population of region n + (…) + population of last region, which should be equal to the country's population.

*Step 4: Calculation of the sampling interval*

The sampling interval *s* should be calculated by dividing the country population by eight (the number of clusters). Example: 1,1177,000 / 8 = 147,125 (Table 1).

*Step 5: Choice of a random number between 1 and the sampling interval*

A number *r* should be selected at random between 1 and the sampling interval (country population divided by eight, the number of clusters). Example: 85,350 (Table 1).

*Step 6: Identification of the clusters*

First cluster: The fourth column should be used to identify the cluster. The first region selected will be the region for which the number of cumulated population size (column 3) is greater than the random number *r*, while the random number *r* is greater then the cumulated population size of the preceding region. The random number *r* should then be marked on the fourth column facing the region. Example: 85,350 is smaller than 100,000 (cumulated population size for region 3) but greater than 70,000 (cumulated population size for region 2), so region 3 is selected (Table 1).

Second cluster: The second region selected will be the region which the number of cumulated population size (column 3) is greater than *r* + *s*, while *r* + *s* is greater than the cumulated population size of the preceding region. The number *r* + *s* should then be marked on the fourth column facing the region. Example: 85,350 + 147125 = 232,475 is smaller than 425,000 (cumulated population size for region 7) but greater than 125,000 (cumulated population size for region 6), so region 7 is selected (Table 1).

Following clusters: Proceeding in the same way eight times, the regions will selected by adding *s* each time to the number on the fourth column, and by identifying the region for which the number of cumulated population size (column 3) is greater than the new number, while the new number is greater than the cumulated population size of the preceding region. In some cases, the new number falls under the same region. In this case, the region is selected twice, and 2 x 10 facilities will be selected from this region. Example: region 7 is selected twice (Table 1).

*Table 1: Example of selection of regions according to the probability proportional to size.*

| Region | | Pop size | Cum pop size | Number | |
|---|---|---|---|---|---|
| Region | 1 | 50'000 | 50'000 | | |
| Region | 2 | 20'000 | 70'000 | | |
| Region | 3 | 30'000 | 100'000 | 85'350 | |
| Region | 4 | 10'000 | 110'000 | | |
| Region | 5 | 5'000 | 115'000 | | |
| Region | 6 | 10'000 | 125'000 | | |
| Region | 7 | 300'000 | 425'000 | 232'475 | 379'600 |
| Region | 8 | 50'000 | 475'000 | | |
| Region | 9 | 60'000 | 535'000 | 526'725 | |
| Region | 10 | **30'000** | **565'000** | | |
| Region | 11 | 120'000 | 685'000 | 673'850 | |
| Region | 12 | 80'000 | 765'000 | | |
| Region | 13 | 90'000 | 855'000 | 820'975 | |
| Region | 14 | 30'000 | 885'000 | | |
| Region | 15 | 20'000 | 905'000 | | |
| Region | 16 | 70'000 | 975'000 | 968'100 | |
| Region | 17 | 52'000 | 1'027'000 | | |
| Region | 18 | 40'000 | 1'067'000 | | |
| Region | 19 | 90'000 | 1'157'000 | 1'115'225 | |
| Region | 20 | 20'000 | 1'177'000 | | |
| **Total** | | **1'177'000** | | | |

**Sampling interval:** **147'125**
**Random number:** **85'350**
**Regions selected:** **3,7(twice),8,11,13,16,19**

Second stage

In each of the eight selected regions, a cluster of 10 healthcare facilities will be selected. (Two additional facilities may be selected in each district to allow replacements if needed). A list of all facilities of the region should be obtained. If a list of facilities cannot be obtained, this sampling methodology is not possible. Two sampling methods can be used: random sampling and systematic sampling.

*Random sampling*

From the list of facilities, F facilities are selected at random using a random number table.

*Systematic sampling*

Healthcare facilities in the region are displayed on a list, and a ranking number is assigned to each facility. The total number of facilities is divided by 10 (the number of healthcare facilities included in the region) to obtain the sampling interval $s'$. Then, a random number $r'$ between 1 and the sampling interval $s'$ is chosen. The healthcare facilities selected will be the one that rank with number $r'$, $r' + s'$, $r' + (2x\ s')$, $r' + (3x\ s')$, etc… until $r' + (9x\ s')$. Note that there sampling intervals $s'$ and ranking numbers $r'$ are different from the one used for the selection of clusters (Stage 1)

**SAMPLE SIZE**

The total sample size will be 8 x 10 = 80 healthcare facilities.

## REPLACEMENTS

Care should be taken to visit all selected facilities without replacement. Replacement should be limited to facilities that are not eligible (e.g., facilities where injections are never given, facilities that have closed, facilities under construction). Replacement of facilities that are difficult to access should be avoided as this could lead to a bias through over-representation of easily accessible facilities that may receive better staffing, equipment, and supplies. Hard-to-reach facilities should be identified at an early stage to plan for supplemental access efforts.

## HUMAN SUBJECTS

Because this tool is designed to evaluate infection control practices during routine healthcare delivery, it should not be considered as research and thus is not subject to an Institutional Review. Board (IRB) or ethical committee approval. In addition, to prevent any ethical issue, surveyors will be asked to intervene to prevent potential harm if they are about to witness injection practices that are of particular danger to the injection recipients (e.g., re-use of syringes and / or needle without sterilization).

## DATA COLLECTION PROCEDURE

Methods that have been used in the past to assess or evaluate injection safety are subject to potential bias. Collecting information on practices reported trough interviews of injection providers is subject to reporting bias, and observation of practices is subject to Hawthorne effect (observer-induced changes in practices). Thus, this tool proposes a method in which information is obtained using a combination of interview and structured observations. Information to be collected include:

1) Structured observation of available supplies;

2) Structured observation of practices;

3) Reported availability of equipment and supplies.

Results obtained using (1), (2), and (3) may be combined to address specific questions. (e.g., the number of injections given every day versus the number of syringes and needle available) will allow cross verifications. A sample data collection instrument is provided in this toolbox (Instrument 1, Page 15).

## IN-COUNTRY PILOT TESTING OF THE DATA COLLECTION INTRUMENT

The three parts of the proposed data collection instrument should be pilot-tested in each country to ensure that it fits the circumstances and that the right nomenclature is used. This pilot testing can be conducted in a few healthcare facilities before training of the fieldworkers. Following pilot-testing, certain minor adaptations of the data collection instrument might be relevant in specific areas according to the type of injection equipment used or other local circumstances. These changes should be kept to the minimum to maintain the standardization.

## RECRUITMENT OF THE FIELD WORKERS

A sufficient number of field workers should be identified so that the fieldwork can be completed in two weeks. For an assessment of 80 facilities using structured sampling, the expected workload of the fieldwork for four teams of one supervisor, one fieldworker, and one driver each is 10 days (Table 2).

*Table 2: Expected workload for the fieldwork for an injection safety assessment of 80 facilities*

| | |
|---|---|
| Time spent in each facility | 2-3 hours |
| Number of facilities visited by one team in one day | 2 |
| Number of facilities to visit by district | 10 |
| Number of working days needed for a team to complete one district | 5 |
| Number of districts to visit | 8 |
| Number of team days work needed | 40 |
| **Number of days of work if 4 teams with 4 vehicles** | **40/4=10 days** |

**TRAINING OF THE FIELD WORKERS**

## Objective

The purpose of the training of fieldworkers is to ensure that all fieldworkers will collect information using the same methodology.

## Initial briefing

Field workers should be trained to collect data in an exhaustive and standardized way while they remain respectful of the healthcare workers and their work. Some background material on injection safety should be provided (available on the www.injectionsafety.org Internet site). The purpose of the assessment and the importance of its sampling methodology should be explained. The data collection instrument should be reviewed with the field workers item by item to ensure that all items are understood and that field workers understand what they need to do. Field workers should be instructed to review data collection instruments for accuracy and completion before leaving a facility.

## Standardization of the data collection procedure

Field workers should be taken to several healthcare facilities to get accustomed to the assessment tool and process. In the first facility, the principal investigator can collect the data himself while explaining what he is doing at each step. In the second facility, while the investigator sill collect data himself, all field workers may collect data on a separate questionnaire to compare results among different observers after the visit. Once fieldworkers feel confident with the tool and results across observers are identical, the team may be split in smaller groups to assess different facilities while still comparing results obtained between various observers in the same facility. This procedure should be continued until the principal investigator is confident that all fieldworkers will collect data in the same way.

Ideally, standardization of the data collection procedure should be conducted in facilities that re not included in the sample. Thus, specific administrative authorizations may be needed in addition to the one obtained for the fieldwork in the selected clusters. In practice, when it is not possible to do otherwise, standardization of the data collection procedure can be conducted in one of the clusters selected for the survey. Because of its large population size, the capital city will often be included in the sample. This provides an opportunity to standardize the data collection procedure across all teams before splitting in smaller groups.

## ORGANIZATION OF THE FIELDWORK

### TIMING OF VISITS

To ensure observation of injections in a high proportion of healthcare facilities, care should be taken to visit healthcare facilities at a time when most injections are given (e.g., early in the morning in sub-Saharan Africa).

### FILLING THE DATA COLLECTION INTRUMENT

#### Introduction

A short word of introduction is proposed as a template that may be adapted. It is important that healthcare workers in the facility know the assessment is confidential, feel comfortable with the assessment, and are aware that they have the right to refuse it.

#### Part 1: Structured observation of equipment and supplies

Part 1 of the instrument is a structured observation of equipment and supplies in the facility. For part 1, fieldworkers may ask the healthcare worker to show the supplies they are looking for, but the form should be filled on the basis of what is observed only and not on the basis of answers that are given.

If the healthcare facility is equipped with a steam sterilizer, it should be tested by boiling water in it to check for steam leaks. In certain situation of limited resources, the healthcare workers may not have resources to purchase kerozene for the sterilizer. Although this information should be collected in the third part of the data collection instrument, field workers should carry small amounts of cash to be able to purchase kerozene so that steam sterilizers can be checked for leaks.

#### Part 2: Structured observation of injection practices

Part 2 should be used for structured observation of injections administered during the visit. When the fieldworkers are about to observe practices that may expose the injection recipient to substantial risks (e.g., use of injection equipment re-used in the absence of sterilization) the procedure should be tactfully interrupted to protect the injection recipient. However, the dangerous procedure that was about to occur should be recorded on the data collection form as if it had actually occurred.

#### Part 3: Interviews with healthcare workers

The questionnaires in part 3 should be used to interview the injection provider and the supervisor of the facility. If there is more than one injection provider in the facility, the one administrating the largest number of injections should be selected. Both questionnaires should be filled on the basis of answers to the questions and not on the basis of the structured observations. Information collected through structured observation (part 1 and 2) and through interviews (part 3) will be compared in the analysis.

## Leaving the facility

After a thank you note and greetings, the instrument should be checked for completeness, accuracy, and understandability before the team leaves the facility.

#### SUPERVISION OF THE DATA COLLECTION

When field workers are sent to the field, they should be supervised during and after data collection. Visits should be done while fieldworkers are collecting data to ensure proper data collection in the field. In addition, in the evening, data collected should be reviewed to ensure for absence of inconsistencies, completeness of data collection forms, and interpretability of the notes.

### DATA ANALYSIS

#### CONFIDENCE INTERVALS

Calculation of confidence intervals and design effects can be done on Epi-Info using the CSAMPLE module.

#### SCORES OF INJECTION SAFETY

## Defining scores

An overall safety score may be calculated for each injection event through attributing values to each of the critical step. Then, values assigned to each critical step can be added to obtain an overall score for each injection. Calculation of the mean score for all observed injections may allow to track changes in injection practices over time using smaller sample sizes. However, scoring procedures should be standardized and validated. The usefulness of scoring should be evaluated through pilot testing of the present tool.

## Critical steps of injection safety

For the purpose of injection safety assessment in the context of EPI, scores will be developed to assess three critical steps of injection safety:

1) The re-use of syringes or needles between patients without sterilization
   (a reflection of the risk of infection for the recipient)

2) Inappropriate waste collection
   (a reflection of the risk of infection for the healthcare worker)

3) Inappropriate waste disposal
   (a reflection of the risk of infection for the community)

While these scores will not reflect all the steps of injection safety, they will constitute a management indicator that can be used to monitor progress of the immunization injection safety efforts of WHO's Immunisation Safety Priority Project (ISPP).

## REPORTING

Injection safety assessment reporting should be reported by healthcare facilities using the standard tables below.

*Tables 3: Suggested reporting format for the injection assessment surveys.*

*Tables 3-A: Information elements reflecting the risk to the recipient*

| Instrument | Item | #/N | % | 95% CI |
|---|---|---|---|---|
| 1- Supplies | Presence of a least one steam sterilizer without observed leaks | XX/XX | XX% | XX-XX |
| 1- Supplies | Presence of all necessary steam sterilizers spare seals | XX/XX | XX% | XX-XX |
| 1- Supplies | Presence of an updated TST spot register | XX/XX | XX% | XX-XX |
| 1- Supplies | Presence of a two-days supply of sterilizable equipment | XX/XX | XX% | XX-XX |
| 1- Supplies | Availability of a week supply of disposable /AD equipment | XX/XX | XX% | XX-XX |
| 2- Practices | Preparation of injections in a dedicated area | XX/XX | XX% | XX-XX |
| 2- Practices | Reconstitution with a sterile syringe and needle | XX/XX | XX% | XX-XX |
| 2- Practices | Reconstitution with recommended diluent (vaccine) | XX/XX | XX% | XX-XX |
| 2- Practices | Reconstitution with recommended diluent (curative) | XX/XX | XX% | XX-XX |
| 2- Practices | Administration with a sterile syringe and needle (vaccine) | XX/XX | XX% | XX-XX |
| 2- Practices | Administration with a sterile syringe and needle (curative) | XX/XX | XX% | XX-XX |
| 2- Practices | Skin preparation before injection (vaccine) | XX/XX | XX% | XX-XX |
| 2- Practices | Skin preparation before injection (curative) | XX/XX | XX% | XX-XX |
| 2- Practices | Removal of needles from multi-dose vials between injections | XX/XX | XX% | XX-XX |
| 2- Practices | Temperature sensitive products kept cool during preparation | XX/XX | XX% | XX-XX |
| 3- Interview | Provision of sufficient energy source for sterilization | XX/XX | XX% | XX-XX |
| 3- Interview | Absence of shortages of disposable injection equipment | XX/XX | XX% | XX-XX |
| 3- Interview | Supply of vaccines with matching quantities of AD syringes | XX/XX | XX% | XX-XX |

*Tables 3-B: Information elements reflecting the risk to the provider*

| Instrument | Item | #/N | % | 95% CI |
|---|---|---|---|---|
| 1- Supplies | Presence of at least 10 sharps containers | XX/XX | XX% | XX-XX |
| 1- Supplies | Absence of pierced, overflowing, or open sharps containers | XX/XX | XX% | XX-XX |
| 1- Supplies | Absence of sharps in open containers | XX/XX | XX% | XX-XX |
| 2- Practices | Absence of two-handed recapping | XX/XX | XX% | XX-XX |
| 2- Practices | Immediate collection of sharps in sharps boxes | XX/XX | XX% | XX-XX |
| 3- Interview | Absence of reported needlestick injuries in the last 12 months | XX/XX | XX% | XX-XX |
| 3- Interview | Absence of shortages of sharps containers | XX/XX | XX% | XX-XX |
| 3- Interview | Provision of sharps containers for vaccination injections | XX/XX | XX% | XX-XX |

*Tables 3-C: Information elements reflecting the risk to the community*

| Instrument | Item | #/N | % | 95% CI |
|---|---|---|---|---|
| 1- Supplies | Absence of sharps around the healthcare facility | XX/XX | XX% | XX-XX |
| 1- Supplies | Absence of full sharps containers in unsupervised areas | XX/XX | XX% | XX-XX |
| 3- Interview | Presence of an healthcare waste management policy | XX/XX | XX% | XX-XX |

## PROPOSED SCHEDULE FOR AN ASSESSMENT OF 80 FACILITIES

In addition to the fieldwork, additional time must be scheduled for preparation and reporting. Overall, completion of the survey should require three weeks to the principal investigator (Table 4).

*Table 4: Proposed overall schedule for an injection safety survey of 80 facilities*

| Day | Proposed activities |
|---|---|
| D1 (Wednesday) | Briefing /pilot testing of the instrument in few facilities |
| D2 (Thursday) | Xeroxing of instrument / Training of the field workers |
| D3 (Friday) | Standardization of the data collection procedure in the first district |
| D4-D5 (week-end) | Break / Travel |
| D6-D10 (Monday - Friday) | Field work |
| D11-D12 (week-end) | Break / Travel |
| D13-D17 (Monday - Friday) | Field work |
| D18-D19 (week-end) | Field work |
| D20 (Monday) | Data entry and analysis |
| D21 (Tuesday) | Debriefing / restitution |

## INSTRUMENT 1: SAMPLE DATA COLLECTION INSTRUMENT TO ASSESS INJECTION SAFETY

### SUGGESTED WORD OF INTRODUCTION *

*[Greetings] My name is _____, and I work with [Institution]. [Institution] is conducting an assessment about injections and health care. To do this survey, we are asking a series of questions and observing supplies as well as injection practices. Your healthcare facility has been chosen at random to take part in this survey. The questions will take approximately 10 minutes to complete, but I will be also observe your working conditions and will be around for about one hour. There is no risk to taking part in this survey, although you might feel you do not want to answer some of the questions. Taking part is your choice; you can choose not to answer any of the questions or tell us to stop at any time. If you decide you do not want to take part, you will not lose any employee benefits that you normally get. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. Please make sure any questions you have are answered before you agree to take part. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.*

If possible, an introduction letter from the Ministry of Health or from the district should be presented.

### STRUCTURED OBSERVATIONS (PART 1 AND PART 2)

Part 1 and part 2 should be used for structured observation (at the beginning of the visit, before questions in part 3 are asked). Part 1 is a structured observation of equipment and supplies in the facility and part 2 covers the injections administered during the visit. For part 1 and 2, you may ask the healthcare worker to show you the supplies you are looking for, but the form **should be filled on the basis of what is observed only and not on the basis of answers that are given**. Information from the healthcare worker will be collected in part 3. If the healthcare facility is equipped with a steam sterilizer, it should be tested by boiling water in it to check for steam leaks (Part 1).

### QUESTIONNAIRE (PART 3 AND PART 4)

The questionnaires in part 3 should be used to interview the injection provider and the supervisor of the facility. If there is more than one injection provider in the facility, the one administrating the largest number of injections should be selected. Both questionnaires should be filled **on the basis of answers to the questions and not on the basis of what you observed.** Information collected through structured observation (part 1 and 2) and through interviews (part 3) will be compared in the analysis.

District (cluster) number: _____ Facility number: _____

Date and time of arrival:_____ Date and time of completion: _____

* This note should be adapted to each country and may be subject to ethical committee review or approval.

**1- STRUCTURED OBSERVATIONS OF EQUIPMENT AND SUPPLIES AVAILABLE AT THE FACILITY**

*I would like to start by observing some of the equipment and supplies available in this facility:* **(This section is based upon observation only)**

| | | | | |
|---|---|---|---|---|
| Re-use of syringes or needles in this facility, either for immunization or for curative injections. | 1- Yes | 2- No | | 3- Cannot be assessed |
| If yes, sterilization methods available (circle all that apply) | 1- Steam sterilizer | 2- Boiling | 3- Both | 4- Other (Specify) _____ |

**IF** pressure sterilizer used in this facility (**If no**, skip next 8 items)

| | | | |
|---|---|---|---|
| Number of steam pressure sterilizers routinely in use | Single rack ____ | Double rack ____ | Triple rack _____ |
| Presence of at least one sterilizer that does not leak during the test | 1- Yes | 2- No | 3- Cannot be assessed |
| Number of spare sterilizer seals available | Number of seals | _____ | 3- Cannot be assessed |
| Number of spare sterilizer safety valves available | Number of valves | _____ | 3- Cannot be assessed |
| Number of spare sterilizer pressure valves available | Number of valves | _____ | 3- Cannot be assessed |
| Presence of a complete, updated register for logging TST spot indicators | 1- Yes | 2- No | 3- Cannot be assessed |
| Presence of a functioning heater(s) for steam pressure sterilizer(s) in the facility | 1- Yes | 2- No | 3- Cannot be assessed |
| Number of complete sterilizable injection equipment kits | ___ Kit A | ___ Kit B | |

| Syringe and needle inventory | Total number of syringes available, including racks and storage | | | | Total number of needles available, including racks and storage | |
|---|---|---|---|---|---|---|
| Size / Type | Sterilizable[1] | Disposable[2] | Auto Disable[3] | Check if can't evaluate | Sterilizable[1] | Check if can't evaluate |
| 0.05 ml | | | | | | |
| 0.5 ml | | | | | | |
| 5 ml | | | | | | |
| For reconstitution | | | | | | |
| Other (specify) | | | | | | |

[1] Number of syringes or needles manufactured for re-sterilization.
[2] Number of disposable syringes and needles in sealed packets or fitted with 2 caps
[3] Number of AD syringes and needles in sealed packets or fitted with 2 caps

| | | | | | | |
|---|---|---|---|---|---|---|
| Number of puncture-proof safety collector containers (sharps boxes) in stock | 0 | 1-4 | 5-9 | 10-20 | ≥ 20 | Cannot be assessed |
| Presence of sharps boxes in areas where injections are given | 1- Yes | | 2- No | | 3- No safety boxes | |
| Presence of overflowing, pierced, or open sharp box(es) | 1- Yes | | 2- No | | 3- No safety boxes | |
| Number of full sharps box(es) waiting for disposal / incineration stored safely | Number present | | _____ | | Cannot be assessed | |
| Number of full sharps box(es) waiting for disposal / incineration stored in unsupervised fashion | Number present | | _____ | | Cannot be assessed | |
| Sharps in an open container, plastic bottles, or other containers exposing to needlestick injuries | 1- Yes | | 2- No | | 3- Cannot be assessed | |
| Evidence of used sharps around the health centre and / or the disposal site | 1- Yes | | 2- No | | 3- Cannot be assessed | |

Type of waste disposal facility used for the disposal of the majority of sharps

**1-** Open burning on the ground
**2-** Open burning in a hole or an enclosure
**3-** Incinerator
**4-** Burial
**5-** Dumping in pit latrine or other secure pit
**6-** Dumping in an unsupervised area
**7-** Transport for off-site treatment

**2- STRUCTURED OBSERVATIONS OF ALL INJECTIONS GIVEN DURING THE VISIT**

*I would now like to see you perform injections or intravenous infusions:* **(This section is based upon observation only)**

| **Type of injection session: 1- Routine 2. Vaccination day** | **Vaccine** | | **Curative** | |
|---|---|---|---|---|
| Injection provider identification (Type A for the first, B for the second, C for the third etc…) | | | | |
| | **"Y" when yes, "N" when no** | | | |
| Use of a dedicated working table or tray, separate from areas contaminated or potentially contaminated with blood * | | | | |
| Type of syringe used (1= AD, 2= disposable, 3= sterilizable) | | | | |
| (**Disposable or AD syringes**) For each injection, use of syringe from sterile packet or fitted with 2 caps † | | | | |
| (**Sterilizable syringes**) or taken from a sterilizer with sterile forceps (if sterilizable) † | | | | |
| For each injection, use of new needle for disposable / AD or taken out of a sterilizer with sterile forceps (if sterilizable) † | | | | |
| Removal of all needles from the vial between injections | | | | |
| For each reconstitution, use of a sterile syringe and needle (from sealed packet, fitted with 2 caps, or taken out of a sterilizer) | | | | |
| (**If vaccine**) Re-constitution of lyophilised vaccines with correct volume of diluent from the same manufacturer | | | | |
| (**If other medication**) Re-constitution of powdered substances with diluent from a single-dose diluent vial | | | | |
| (For heat sensitive vaccines and medications only) Vial kept between 2°C and 8°C during period of use | | | | |
| Skin cleaning before injection | | | | |
| **If yes**, type of swab: 1= Sterile water swab; 2= Disinfectant swab; 3= Swab that is dirty, blood stained, or soaked in a open pot); 4=other (specify) | | | | |
| Reconstituted vaccines and other perishable medications discarded at the end of the session | | | | |
| Two-hands re-capping of the needle after the injection (compared to other items on the checklist, two-hands recapping is an undesirable practice) | | | | |
| (**Disposable or AD syringes**) Collection in a puncture-proof safety container immediately after the injection | | | | |
| (**Sterilizable syringes**) Flushing, disassembling, and dropping of syringe and needle immediately after use into bowl containing enough water to cover them | | | | |

* Area also used for procedures that may lead to blood contamination (e.g., blood sampling, wound dressing etc.)

† If re-use of injection equipment is about to occur without sterilization, intervene to interrupt the procedure as tactfully as possible and a "Y" should be marked on the checklist.

**3A- INTERVIEW OF INJECTION PROVIDER AND SUPERVISOR***

*I would like to ask you a few questions about how you give injections (injection provider)*

| | | | | | | |
|---|---|---|---|---|---|---|
| *How many injections are given per week on average in your facility?* | ____ Immunisations / week | | ____ Other injections / week | | | |
| | *Circle Answer* | | | | | |
| *Do patients provide their own injection equipment for vaccination?* | 1- Always | 2- Sometimes | 3- Never | 4- Don't know | | |
| *Do patients provide their own injection equipment for therapeutic injections?* | 1- Always | 2- Sometimes | 3- Never | 4- Don't know | | |
| *Are new, disposable syringes and needles available for purchase in this community?* | 1- Yes | 2- No | 3- Don't know | | | |
| *Do you use needle removers or needle cutters?* | 1- Yes | 2- No | 3- Don't know | | | |
| *How many accidental needle sticks have you had in the last12 months?* | _____ Accidental needlesticks in the last year | | | | | |

**Sterilizable or Re-utilized Syringes**

| | | | | | | |
|---|---|---|---|---|---|---|
| *When was the steam sterilizer seal /gasket last changed?* | < 1 month | < 6 month | < 1 year | > 1 year | 5- Don't know | 6- N/A † |
| *When was the steam sterilizer safety valve last changed?* | < 1 month | < 6 month | < 1 year | > 1 year | 5- Don't know | 6 - N/A † |
| *When was the steam sterilizer pressure valve last changed?* | < 1 month | < 6 month | < 1 year | > 1 year | 5- Don't know | 6 - N/A † |
| *Are you provided with sufficient kerosene, other energy source, or funds to purchase it through your health services?* | 1- Yes | 2- No | 3- Don't know | | | |
| *Do you re-sharpen needles after a certain number of injections or when blunt?* | 1- Yes | 2- No | 3- Don't know | | | |

* If more than one injection provider in the facility, select the one administrating the largest proportion of injections

† E.g., if the sterilizer is too recent to require spare parts changes

**3B- INTERVIEW OF INJECTION SUPERVISOR**

*I would like to ask you a few questions about your policy and your supplies (supervisor)*

| | | | | | |
|---|---|---|---|---|---|
| *Do you have a copy of the injection safety policy /recommendations issued by your health services?* | 1- Yes | 2- No | 3- Don't know | | |
| *Do you have a copy of the safe sharps and healthcare waste disposal policy issued by your health services?* | 1- Yes | 2- No | 3- Don't know | | |
| **Sterilizable or Re-utilized Syringes** | | | | | |
| *In the last year, how long in total have you been out of kerosene*[*] | Never | < 1 month | < 3 month | ≥ 3 month | 4- Don't know |
| **Disposable or AD Syringes** | | | | | |
| *In the last year, how long in total have you been out of new, disposable syringes and needles?* | Never | < 1 month | < 3 month | ≥ 3 month | 4- Don't know |
| *In the last year, how long in total have you been out of puncture-proof, sharps container?* | Never | < 1 month | < 3 month | ≥ 3 month | 4- Don't know |
| *Are stocks of vaccines delivered with matching quantities of injection equipment?* | 1- Yes | 2- No | 3- Don't know | 4- No vaccinations here | |
| *Are stocks of vaccines delivered with matching quantities of puncture-proof sharps containers?* | 1- Yes | 2- No | 3- Don't know | 4- No vaccinations here | |

***Thank you very much for your time. Your participation in this survey will be useful in improving injection practices in this***

[*] *Or other energy source for sterilization*

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WORLD HEALTH ORGANIZATION (WHO)

BASIC SUPPORT FOR INSTITUTIONALIZING CHILD SURVIVAL II (BASICS II)

SAFE INJECTION GLOBAL NETWORK (SIGN)

# TOOL "D" TO ASSESS THE ASSOCIATION BETWEEN INJECTIONS AND INFECTIONS

THIS DOCUMENTS IS PART OF A TOOLBOX TO ASSESS AND EVALUATE INJECTION PRACTICES. THE COMPLETE TOOLBOX INCLUDE THE RAPID ASSESSMENT AND RESPONSE GUIDE AND FOUR ADDITIONAL TOOLS (A, B, C, AND D)

This toolbox addresses broad concepts of assessment and evaluation of injection practices that were discussed during a workshop of expert consultants held at BASICS, Arlington, VA, USA in March 2000. It constitutes a dated draft circulated for comments and suggestions. Although it is made widely available at an early stage, it is not yet intended to be a "how-to" manual for field use. Later versions of this document will be adapted for wider readership level once consensus has been reached on broad concepts and after field testing.

Comments and suggestions should be directed to the Secretariat of the Safe Injection Global Network (SIGN), World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, Geneva 27, Switzerland 1211. Fax +41 22 791 4836. E-mail: sign@who.ch.

| **Intended use and proposed timeline for this document** | |
|---|---|
| Preparation of draft 1 by selected consultants | February 22, 2000 |
| Review of the draft 1 by a group of experts and preparation of draft 2 | April 30th, 2000 |
| Review of draft 2 by workshop participants to prepare draft 3 | May 31st, 2000 |
| Field testing of draft 3 in few countries to prepare draft 4 | September 1st, 2000 |
| Wider dissemination of draft 4 for broad use and ongoing feedback | 2000-2002 |
| Preparation of a final version after two years of feedback from the field | End of 2002 |

## D- TOOL TO ASSESS THE ASSOCIATION BETWEEN INJECTIONS AND INFECTIONS

### INTRODUCTION

Injections have been associated with adverse events, including abscesses, [1] infections with bloodborne pathogens, [2] poliovirus associated provocation paralysis, [3] oral polio vaccine-associated provocation paralysis, [4] and paralyses secondary to sciatic nerve lesions. [5] Among these adverse events, infections with bloodborne pathogens, including HBV, HCV, and HIV are associated with the heaviest burden of diseases and deaths. [6,78,9,10] However, that burden is not immediately apparent since the initial phase of infection with bloodborne pathogens is frequently asymptomatic. Thus, epidemiological studies should conducted locally to assess the association between injections and infections and to provide the evidence upon which policies for safe and appropriate use of injections can be based.

### PURPOSE OF THE TOOL

The purpose of this tool is to provide suggestions regarding methods to conduct an initial assessment of the association between injections and infections.

### CONDUCTING AN INITIAL ASSESSMENT OF THE ASSOCIATION BETWEEN INJECTIONS AND INFECTIONS

Methods are available regarding abscesses and infections with bloodborne pathogens.

#### ABSCESSES

**Caution is advised when using abscesses as an indicator of injection safety.** First, abscesses do not represent the majority of the burden of disease associated with unsafe injection practices. Second, the breaks in infection control practices that may cause abscesses may differ from the breaks in infection control practices that may lead to transmission of bloodborne pathogens (e.g., abscesses may result from a failure to decontaminate the skin which may bear no substantial risk of cross infection with bloodborne pathogens). Finally, there is little experience regarding the feasibility and usefulness of abscess surveillance.

When abscess surveillance is conducted, it should be conducted in an exploratory way so that experience can be recovered regarding the feasibility and usefulness of such a system. If possible, abscess surveillance should be conducted in conjunction with information collection regarding the incidence of injection-associated infections with bloodborne pathogens so that the relationship between the incidence of injection-associated abscesses and the incidence of injection-associated infection with bloodborne pathogens can be assessed.

## Objectives

The objectives of studies to assess the association between injections and abscesses are to:

1) Estimate the incidence of injection-associated abscesses in a population;

2) Identify the type of injections that lead to injection-associated abscesses.

## Case definition

An abscess is defined as a subcutaneous collection of pus that develops within two weeks at the site of an injection, excluding other potential inoculation modes (e.g., injuries, surgery).

## Study design

Stimulated passive surveillance

## Population under surveillance

Because a population-based estimate of the incidence of abscesses is needed, surveillance data should be linked to a well-defined population base of known population size. This population base may be:

1) Exhaustive (e.g., all healthcare facilities to cover the population of a district or a country);

2) Sentinel (e.g., selected healthcare facilities that capture a well-defined reference population base. Taken together, these well-defined population bases constitute a sentinel group that can be used to infer what the situation may be for the total population).

## Data collection

Healthcare workers can collect information on abscess report forms (Instrument 1, Sample case report form for abscess surveillance, Page 11) distributed in healthcare facilities for prospective or retrospective surveillance.

## Data analysis

The number of abscesses should be added and divided by the total area population size for the calculation of a population-based annual incidence [1].

### INFECTIONS WITH BLOODBORNE PATHOGENS

## Objectives

For bloodborne pathogens, the objectives of studies to assess the association between infections and injections are to:

1) Determine whether infections with bloodborne pathogens are associated with injections;

2) Estimate the strength of the association between infection with bloodborne pathogens and injections;

3) Estimate the proportion of new cases of infection with bloodborne pathogens that may reasonably be attributable to unsafe injection practices (i.e., by the calculation of the population attributable risk [11]).

## Study population

Study population should be chosen so that the conclusions of the study can be generalized. The study population may be the general population (e.g., residents of a certain area) or subgroups of particular importance (e.g., hospitalized patients, children). Use of individuals who can be accessed and studied easily but cannot be identified as a population group should be avoided (e.g., blood samples available from a bank of serum).

## Choice of a pathogen

The bloodborne pathogen(s) of interest should be chosen according to the incidence and prevalence of the various bloodborne pathogens in the study area. In most cases, the bloodborne pathogen of interest will be HBV, HCV, or HIV as injection-associated infections with other bloodborne pathogens (e.g., viral haemorrhagic fevers) usually occur as time-limited outbreaks.

## Choice of a type of infection

Strengths and weaknesses of the use of recent versus past or present infections for studies assessing the association between injections and infections with bloodborne pathogens are summarized in Table 1.

*Table 1: Strengths and weaknesses of use of recent versus past or present infections for epidemiological studies*

| | **Types of infection to be studied** | |
|---|---|---|
| | **Recent (incident)** | **Past or present (prevalent)** |
| Logistical feasibility | Difficult | Easier |
| Disease frequency requirement | High incidence | High prevalence |
| HBV infection studies | Marker of recent infection available | Marker of chronic infection available |
| HCV infection studies | Marker of recent infection not available | Marker of chronic infection available |
| HIV infection studies | Marker of recent infection available but clinical syndrome aspecific | Marker of chronic infection available |
| Referent exposure period | Based upon incubation of infection | Lifetime (or surrogate) |
| Quality of scientific evidence | Best | Approximate |
| Estimation of population attributable risk | Best | Approximate |

Recent infections

Use of recent infections is adapted to high incidence situations. Because the exposure of interest has occurred in the recent past, studies of recent (incident) infections (in cohort or case-control studies) are methodologically more appropriate, provide better epidemiological

evidence, and allow precise calculation of population attributable risks. However, they are more difficult to conduct, and incident cases of recent infection may be difficult to identify because a non-specific clinical syndrome (e.g., acute HIV infection) or because of the absence of a serological marker of recent infection (e.g., recent HCV infection).

Past or present infections

Use of past or present infections is adapted to high prevalence situations. Because cases are easier to identify, studies of past or present (prevalent) infections (in cross-sectional and case-control studies) are easier to conduct and may provide sufficient evidence to justify a safe and appropriate use of injection policy. However, they are subject to a number of limitations and they only allow an approximate calculation of population attributable risks.

## Case definitions

Case definition for infections with bloodborne pathogens should include criteria based upon clinical features and criteria based upon serological diagnosis.

HBV infection

*Recent infection*

The following case definition of acute hepatitis B should be used:

- Acute illness with jaundice (and, if available, elevated aminotransferase activity, at least 5 times the upper limit of the laboratory normal value);
- Positive IgM antibody to the hepatitis B core antigen (anti-HBc IgM) test.

*Past or present infection*

- Positive total anti-HBc antibody test

HCV infection

*Recent infection*

Because of the absence of a serological marker of recent HCV infection, the case definition for recent HCV infection should aim at capturing cases of acute, non A, non B hepatitis that are antibody to hepatitis C virus (anti-HCV) positive:

- Acute illness with jaundice and elevated aminotransferase activity (at least 7 times the upper limit of the laboratory normal value)
- Negative IgM antibody to hepatitis A virus (anti-HAV IgM) test
- Negative anti-HBc IgM test
- Negative antibody to hepatitis E virus (anti-HEV) test *
- Positive anti-HCV EIA test
- Positive supplemental anti-HCV test (e.g., RIBA) †

*Past or present infection*

- Positive anti-HCV EIA test
- Positive supplemental anti-HCV test (e.g., RIBA) †

HIV infection

*Recent infection*

The non-specific characteristics of acute HIV infection makes it difficult to use acute HIV infection as an indicator.

* In countries where HEV is endemic or when patients have travelled to HEV endemic countries

† May be avoided if a second or third generation test was used and if the prevalence of HCV infection in the population was high (exceeds 5%)

*Past or present infection (in adults, adolescents, or children >= 18 months*
Laboratory criteria

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme immunoassay), followed by a positive results on a confirmatory (sensitive and more specific) test for HIV antibody (e.g., Western blot or immunofluorescence antibody test) *

Or

- Positive result or report of a detectable quantity on any of the following HIV virologic (non-antibody) tests:
  - HIV nucleic acid detection
  - HIV P 24 test
  - HIV isolation (viral culture)

Or clinical or other criteria

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician

Or

- Conditions that meet criteria included in the case definition for AIDS.

## Study designs

Analytic cross-sectional studies

*Principle*

Cross sectional studies (surveys) may be used to assess the association between past or present infection with bloodborne pathogens and injections if:

1) Serum samples were collected for the diagnosis of past or present infection with bloodborne pathogens;

2) Relevant epidemiological information was collected regarding potential exposures, including use of injections;

3) Sampling methods used for the survey ensure that the study sample is representative from the study population (e.g., cluster sampling [**Error! Bookmark not defined.**]).

Because past or present infection with bloodborne pathogen in a study participant may have been caused by any exposure that occurred during lifetime, information regarding lifetime exposure histories should theoretically be collected. However, different surrogate referent exposure period may de defined as judged appropriate (e.g., past year, past 5 years, past 10 years) [12].

The prevalence of the serological markers of past or present infection with bloodborne pathogen may be studied according to the distribution of various exposures for the calculation of prevalence ratios. Such studies have been conducted to evaluate the association between the lifetime history of injections and the presence of serological indicators of present or past infection with HBV [13], HCV [12], or HIV [14,15].

*Advantages*

Cross sectional studies are the least complicated to conduct and are useful to obtain the evidence of an association between past or present infection with bloodborne pathogens and injections. Cross sectional studies are also useful when symptoms of initial infection are rare

* New saliva-based or urine-based test are now available for the diagnosis of HIV infection.

and non-specific (e.g., HIV infection) or when serological makers of recent infection are not available (e.g., HCV infection). Cross sectional studies are particularly relevant for young children since 1) information regarding lifetime exposure histories may be easier to collect and 2) the much narrower time window of exposure decreases the probability of misclassification of the appropriate time period. However, for studies conducted among young children, a serological assessment of the status of the mother might be needed to sort out perinatal transmission.

*Limitations*

Cross sectional studies are limited because past or present infection with bloodborne pathogen in a study participant may have been caused by an exposure that occurred at any moment during lifetime. Use of lifetime as the referent exposure period may lead to imprecision in the recall of exposure and in the estimation of the strength of the association. In addition, cross sectional studies can only provide prevalence ratio estimates. Calculation of risk ratios and of population attributable risks is not directly possible but may be attempted through the use of advanced epidemiological methods.

**Overall, caution is advised when planing, conducting, or analysing cross sectional studies to study the association between infections and injections.** While these studies are not demanding in terms of time and resources, they require substantial expertise not to be misinterpreted. The multiple criteria that are needed to conclude in favour of a causal relationship between an exposure and an outcome should be checked, including:

- The strength of the association;
- The presence of a dose-response relationship;
- The consistency among results of different studies;
- The biological plausibility.

Case-control studies

*Principle*

In case-control studies, cases of infection with bloodborne pathogens and unaffected controls are compared for the frequency of various exposures, including injections. When recruited cases are recent, incident cases, such studies [4] can provide rapid estimates of the relative risk of infection with bloodborne pathogens for persons exposed to injections. Relative risks can then be used to calculate population attributable risks. The following issues that are practical consequences of the principles of case-control studies [16] should be given consideration:

1) When possible (see Table 1), cases of adverse events should be recent, incident cases (as opposed to past or present, prevalent cases);

2) When recent, incident cases are used, information should be collected regarding potential exposures, including injections, during a referent exposure period that should be compatible with the incubation period or the natural history of infection (e.g.; two to six months before illness in the case of recent hepatitis B or C virus infection);

3) Control-subjects should be susceptible to the adverse event studied (e.g., control-subjects should be anti-HBc negative in the case of acute hepatitis B and anti-HCV negative in the case of acute hepatitis C);

4) Appropriate information collection and analysis should control confounding factors* that might confound the association between an adverse event and injections (e.g., age, blood transfusions, other healthcare related exposures, and sexual practices).

*Use of viral hepatitis surveillance data*

When acute viral hepatitis B or C is used as an indicator, acute hepatitis cases reported through surveillance may be used to nest case-control studies [16] where reported hepatitis A cases are used as a control group for reported acute hepatitis B and or C cases. The calculation of this odd ratio should be adjusted for potential confounding factors including age and socio-economic status. In addition, routine use of hepatitis A cases as controls should be validated through the initial recruitment of a second population-based control group. If conducted appropriately, this method allows evaluating the association between acute hepatitis B and or C and injections and calculating a population attributable risk (Table 2). In addition, because surveillance is based upon ongoing information collection systems, this method allows monitoring the strength of this association over time, which can be used to evaluate prevention programs (See evaluation, page **Error! Bookmark not defined.**).

While exhaustive surveillance may be difficult to conduct and expensive in a whole country, sentinel surveillance in a limited number of districts or hospitals selected to represent the country may be sufficient to obtain information for action.

Similarly, if ongoing collection of information through viral hepatitis surveillance cannot be maintained, surveillance may be conducted intermittently at regular time interval to conduct nested case control analysis where cases of recent hepatitis B or C virus infections are compared to cases of non B-non C acute hepatitis.

*Table 2: Association between acute hepatitis B and injections among unvaccinated children reported with acute hepatitis, Romania, 1997-1998 [10].*

| | Reported, serologically confirmed acute hepatitis cases | | | |
|---|---|---|---|---|
| | Hepatitis B cases | Hepatitis A controls | Odds ratio | 95% confidence interval |
| Received an injection | 15/32 (47%) | 33/288 (11%) | 6.8 | 1.8-16 |

In addition to the basic attributes of a surveillance system [17], surveillance systems need to meet certain requirements to be used to assess or evaluate the association between viral hepatitis and injections, including:

1) The surveillance system should base diagnosis of acute viral hepatitis A and B upon serological markers of recent infection (IgM anti-HAV and IgM anti-HBc);

* Confounding factors (e.g., hospitalization) distort the association between the exposure and the outcome because they are associated with the exposure (e.g., injections) and the outcome of interest (e.g., hepatitis). An apparent association between injections and hepatitis could be explained by hospitalisation: hospitalisation can cause infections through nosocomial transmission and hospitalised patients are more likely to have received injections.

2) Reliable information regarding potential risk factors for infection during the referent exposure period (e.g., receiving injections) and the vaccination status against hepatitis B, should be routinely collected on case report forms;

3) Investigators who collect information regarding exposures for reported cases should not be aware of the serological diagnosis of the hepatitis patients.

*Advantages*

Case control studies are easy to conduct. When conducted using recent, incident cases, they allow estimations of relative risks and population attributable risks.

*Limitations*

Case control studies are subject to recruitment and information bias and should be conducted according to the general principles of case control studies [16].

Cohort studies

*Principle*

In cohort studies, the incidence of infections is compared for subjects followed over time who are exposed or unexposed to selected exposures, including injections. In addition to the occurrence of an acute illness meeting the case definition for recent HBV, HCV, or HIV infection, evidence of seroconversion among participants identified as susceptible on a previous serological test represents evidence of recent infection.

*Advantages*

Cohort studies are less sensitive to bias than cross sectional or case-control studies. They provide the best estimate of the strength of the association between injections and infections through estimation of the relative risk and of the population attributable risk. They may be easy to conduct in specific settings where the risk of infection is high and the information is readily available for well-defined populations [7] (e.g., patients who will be exposed to a high number of injections or infusions in hospitals).

*Limitations*

Obstacles to conducting cohort studies include duration of follow up, low incidence of infection with bloodborne pathogens, and costs of follow up that includes repeated serological testing. Thus, in many developing country settings, cohort studies would require too much time and resources and would delay interventions if they were the only source of evidence upon which prevention activities can be decided.

## Data collection

Sample templates that may be used to formulate data collection instruments are shown in the appendix. These sample include a template for cross sectional surveys (Instrument 2, Page 12), a template for incident case control studies (Instrument 3, Page 15), and a template for a hepatitis case report form that can be used to nest case control studies within surveillance data (Instrument 4, Page 19). Questionnaires for cohort studies can be constructed on the basis of these templates according to the frequency and length of follow up.

## Data analysis

Data analysis should aim at the calculation of measures of association, including prevalence ratios (cross sectional studies), odds ratios (case-control studies), and risk ratios (cohort studies). Confounding factors should be controlled through adjustment, restriction, matching,

and logistic regression as appropriate. Population attributable risk calculation should be attempted, although they are theoretically limited to studies involving recent, incident cases.

## HUMAN SUBJECTS

Depending on local institutions, final study design, objectives, and data collection, studies conducted on the basis of this tool:

- May or may not be considered as research;
- May or may not be subject to an Institutional Review. Board (IRB) approval.

Institutions taking responsibility for these studies should check locally to determine whether any ethical counsel or approval is needed or not before conducting the study.

**INSTRUMENT 1: SAMPLE CASE REPORT FORM FOR ABSCESS SURVEILLANCE**

For the purpose of surveillance, an abscess is defined as a subcutaneous collection of pus that develop within two weeks at the site of an injection

District::
City / village:
Healthcare facility identification:
Recall period: From: / / to / /
Estimated population for the catchment area:
Date of completion of the report
Type of surveillance:
1- Prospective
2- Retrospective

| ID | Date of onset *(dd/mm/yy)* | Place of residence | Age (years) | Gender (M/F) | Suspected cause (Tick as appropriate) | | | | Referral | Comments (specify if aseptic) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Injection by healthcare workers | | Injection by informal providers | Other causes | | |
| | | | | | Quinine | Others | | | | |
| | | | | | | | | | | |
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**INSTRUMENT 2: SAMPLE QUESTIONNAIRE FOR ANALYTICAL CROSS SECTIONAL STUDIES**

**SUGGESTED WORD OF INTRODUCTION** [*]

*[Greetings] My name is _____, and I work with [Institution]. [Institution] is doing a study about diseases that may be caused by unsafe injections. To do this survey, we are asking a series of questions any injections you may have received and about diseases that you may or may not have presented. You have been chosen at random to take part in this study. The questions will take about 10 minutes to complete. There is no risk to taking part in this study, although you might feel you do not want to answer some of the questions. Taking part is your choice; you can choose not to answer any of the questions or tell us to stop at any time. If you decide you do not want to take part or if you want to skip a question, you will not lose any of the healthcare benefits that you normally get. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. Please make sure any questions you have are answered before you agree to take part. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.*

**(Please note that an additional consent form may be needed if blood is taken for the purpose of the study)**

**QUESTIONS FOR ALL STUDY PARTICIPANTS**

| | | | | |
|---|---|---|---|---|
| Status: | | | 1- Case | 2- Control |
| 1. | Date of birth: | Day ___ | Month ___ | Year ___ |
| 2. | Gender: | | 1- Male | 2- Female |
| 3. | District of residence: | | | |
| 4. | How many persons live in this household? | ____ >= 15 y | ___ < 15 y | |
| 5. | What is the monthly income of this household? | ____ | (Currency) | |
| 6. | Do you receive daily insulin injections for diabetes? | 1- Yes | 2- No | 3- Don't kw |
| 7. | Do you have any clotting factor disease such as hemophilia? | 1- Yes | 2- No | 3- Don't kw |
| 8. | Do you receive hemodialysis for renal disease? | 1- Yes | 2- No | 3- Don't kw |
| 9. | Is someone in your household chronically infected with hepatitis B? | 1- Yes | 2- No | 3- Don't kw |
| 10. | Were you vaccinated against hepatitis B? | 1- Yes | 2- No | 3- Don't kw |
| 11. | If yes, how many doses have you received? | ____ | Doses | |

[*] This note should be adapted to each country and subject to ethical committee review or approval.

**During the last year:**

| | | | |
|---|---|---|---|
| 12. How many injections have you received for vaccinations? | | ____ | Injections |
| 13. How many other injections have you received from healthcare workers for any other reason? | | ____ | Injections |
| 14. How many injections for other reasons by informal injection providers and traditional healthcare workers? | | ____ | Injections |
| *Calculate total number of injections and report to the patient* | | | |
| What you tell me means that, in the last year, you have received | | ____ | Injections |
| 15. Consider the five years preceding this year, did you receive more injections, less injections, or the same number of injections on average per year in that period than in the past year? | 1- More | 2- Less | 3- The same |
| 16. Ignoring the last year and considering the preceding five years, how many injections do you think you received, on average, per year: | | ____ | Injections |
| 17. Ignoring the last year and considering the preceding ten years, how many injections do you think you received, on average, per year: | | ____ | Injections |

**During your whole life:**

| | | |
|---|---|---|
| 18. How many times have you ever had a blood test? | ____ | Times |
| 19. How many times have you ever been in the hospital? | ____ | Times |
| 20. How many times have you ever received a blood transfusion? | ____ | Times |
| 21. How many times have you ever been put to sleep for surgery? | ____ | Times |
| 22. How many times have you ever had surgery without being put to sleep? | ____ | Times |
| 23. How many times have you ever been to the dentist? | ____ | Times |
| 24. How many times have you ever had acupuncture? | ____ | Times |
| 25. How many times have you ever had tuberculosis skin tests? | ____ | Times |
| 26. How many times have you ever had ear or body piercing? | ____ | Times |
| 27. How many times have you ever had tattoos? | ____ | Times |
| 28. How many times have you ever had you head shaved? | ____ | Times |
| 29. Have you ever been circumcised? | 1- Yes | 2- No |

**ADDITIONAL QUESTIONS FOR CHILDREN UNDER 15 YEARS OF AGE**

*The three next questions should be asked to the mother of the child:*

| | | | |
|---|---|---|---|
| 30. Do you have chronic hepatitis B? | 1- Yes | 2- No | 3- Don't kw |
| 31. Do you have chronic hepatitis C? | 1- Yes | 2- No | 3- Don't kw |
| 32. Are you infected with the HIV/AIDS virus? | 1- Yes | 2- No | 3- Don't kw |

**ADDITIONAL QUESTIONS FOR ADULTS (15 YEARS OF AGE OR OLDER)**

**During your whole life:**

| | | | |
|---|---|---|---|
| 33. Have you ever injected illicit drugs? | 1- Yes | 2- No | 3- Don't kw |
| 34. Did you ever come in contact with syringes and needles during in your workplace? | 1- Yes | 2- No | 3- Don't kw |
| 35. How many times have you ever donated blood or plasma? | | ____ | Times |
| 36. How many sexual partners of the opposite sex have you ever had? | | ____ | Partners |
| 37. How many sexual partners of the same sex have you ever had? | | ____ | Partners |

**INSTRUMENT 3: SAMPLE QUESTIONNAIRE FOR CASE CONTROL STUDIES**

**SUGGESTED WORD OF INTRODUCTION** [*]

*[Greetings] My name is _____, and I work with [Institution]. [Institution] is doing a study about diseases that may be caused by unsafe injections. To do this survey, we are asking a series of questions any injections you may have received and about diseases that you may or may not have presented. You have been chosen at random to take part in this study. The questions will take about 10 minutes to complete. There is no risk to taking part in this study, although you might feel you do not want to answer some of the questions. Taking part is your choice; you can choose not to answer any of the questions or tell us to stop at any time. If you decide you do not want to take part or if you want to skip a question, you will not lose any of the healthcare benefits that you normally get. Your name will not be kept on the forms we use to write down your answers. If we write the results of the survey in a report, you will never be identified in the report. Please make sure any questions you have are answered before you agree to take part. If you have any questions about the survey you may ask them now or you can contact _____ and ask them before you agree to take part.*

**(Please note that an additional consent form may be needed if blood is taken for the purpose of the study)**

**QUESTIONS FOR ALL STUDY PARTICIPANTS**

| | | | | |
|---|---|---|---|---|
| Status: | | | 1- Case | 2- Control |
| 1. | Date of birth: | Day ___ | Month ___ | Year ___ |
| 2. | Gender: | | 1- Male | 2- Female |
| 3. | District of residence: | | | |
| 4. | Date of onset (cases)/ recruitment (controls) | Day ___ | Month ___ | Year ___ |
| 5. | How many persons live in this household? | ____ >= 15 y | ___ < 15 y | |
| 6. | What is the monthly income of this household? | ____ | (Currency) | |
| 7. | Do you receive daily insulin injections for diabetes? | 1- Yes | 2- No | 3- Don't kw |
| 8. | Do you have any clotting factor disease such as hemophilia? | 1- Yes | 2- No | 3- Don't kw |
| 9. | Do you receive hemodialysis for renal disease? | 1- Yes | 2- No | 3- Don't kw |
| 10. | Is someone in your household chronically infected with hepatitis B? | 1- Yes | 2- No | 3- Don't kw |
| 11. | Were you vaccinated against hepatitis B? | 1- Yes | 2- No | 3- Don't kw |
| 12. | If yes, how many doses have you received? | ____ | Doses | |

[*] This note should be adapted to each country and subject to ethical committee review or approval.

**During the two to six months before symptoms (cases) or recruitment (controls):**

| | | | |
|---|---|---|---|
| 13. How many injections have you received for vaccinations? | ____ | | Injections |
| 14. How many other injections have you received from healthcare workers for any other reason? | ____ | | Injections |
| 15. How many injections for other reasons by informal injection providers and traditional healthcare workers? | ____ | | Injections |
| 16. How many times have you ever had a blood test? | ____ | | Times |
| 17. How many nights have you ever been in the hospital? | ____ | | Times |
| 18. How many times have you ever received a blood transfusion? | ____ | | Times |
| 19. How many times have you ever been put to sleep for surgery? | ____ | | Times |
| 20. How many times have you ever had surgery without being put to sleep? | ____ | | Times |
| 21. How many times have you ever been to the dentist? | ____ | | Times |
| 22. How many times have you ever had acupuncture? | ____ | | Times |
| 23. How many times have you ever had tuberculosis skin tests? | ____ | | Times |
| 24. How many times have you had ear or body piercing? | ____ | | Times |
| 25. How many times have you had tattoos? | ____ | | Times |
| 26. How many times have you had your head shaved? | ____ | | Times |
| 27. Have you been circumcised? | 1- Yes | | 2- No |

**ADDITIONAL QUESTIONS FOR CHILDREN UNDER 15 YEARS OF AGE**

*The three next questions should be asked to the mother of the child:*

| | | | |
|---|---|---|---|
| 28. Do you have chronic hepatitis B? | 1- Yes | 2- No | 3- Don't kw |
| 29. Do you have chronic hepatitis C? | 1- Yes | 2- No | 3- Don't kw |
| 30. Are you infected with the HIV/AIDS virus? | 1- Yes | 2- No | 3- Don't kw |

**ADDITIONAL QUESTIONS FOR ADULTS (15 YEARS OF AGE OR OLDER)**

**During the two to six months before symptoms (cases) or recruitment (controls):**

| | | | |
|---|---|---|---|
| 31. Have you injected illicit drugs? | 1- Yes | 2- No | 3- Don't kw |
| 32. Did you come in contact with syringes and needles during in your workplace? | 1- Yes | 2- No | 3- Don't kw |
| 33. How many times have you donated blood or plasma? | ____ | | Times |
| 34. How many sexual partners of the opposite sex have you had? | ____ | | Partners |

35. How many sexual partners of the same sex have you had? ____ Partners

**INSTRUMENT 4: SAMPLE CASE REPORT FORM FOR VIRAL HEPATITIS SURVEILLANCE**

## General characteristics – Identification

| | | | | | |
|---|---|---|---|---|---|
| Date of reporting: / / | | | ID: | District: | |
| Last name: | | | First name: | | |
| Date of birth: / / | | | Gender: | 1- Male | 2- Female |
| Case patient's education years: ___ yrs | | | Number of children in the households: ___ | | |
| Prison: | 1- Yes | 2- No | Number of adults in the household: ___ | | |

## Clinical characteristics

| | | | | | | |
|---|---|---|---|---|---|---|
| Onset date: / / | | | **Serological testing** | | | |
| Hospitalization: | 1- Yes | 2- No | HAV IgM | 1- Pos | 2- Neg | 3- Unk |
| Jaundice: | 1- Yes | 2- No | HBc IgM | 1- Pos | 2- Neg | 3- Unk |
| Death: | 1- Yes | 2- No | Anti HCV | 1- Pos | 2- Neg | 3- Unk |
| ALAT: | | IU/ litre | Anti HEV | 1- Pos | 2- Neg | 3- Unk |

## Exposures in the two to six weeks before onset

| | | | |
|---|---|---|---|
| Involved in a common source outbreak: | 1- Yes | 2- No | 3- Unknown |
| Attendance or work in a day-care: | 1- Yes | 2- No | 3- Unknown |
| Contact with a case of hepatitis A: | 1- Yes | 2- No | 3- Unknown |
| Raw shellfish consumption: | 1- Yes | 2- No | 3- Unknown |
| Consumption of untreated surface water: | 1- Yes | 2- No | 3- Unknown |
| Consumption of untreated well water: | 1- Yes | 2- No | 3- Unknown |

## Exposures in the two to six months before onset

| | | | |
|---|---|---|---|
| Number of injections / infusions: | Vaccination: _____ | Others: _____ | |
| Injections by informal / traditional providers : | 1- Yes | 2- No | 3- Unknown |
| Hospitalization: | 1- Yes | 2- No | 3- Unknown |
| Surgery: | 1- Yes | 2- No | 3- Unknown |
| Blood transfusion: | 1- Yes | 2- No | 3- Unknown |
| Haemodialysis: | 1- Yes | 2- No | 3- Unknown |
| Dentist visit: | 1- Yes | 2- No | 3- Unknown |
| Injection drug use: | 1- Yes | 2- No | 3- Unknown |
| Occupational exposure to blood: | 1- Yes | 2- No | 3- Unknown |
| Skin piercing / barber / circumcision: | 1- Yes | 2- No | 3- Unknown |
| Tattoos or acupuncture: | 1- Yes | 2- No | 3- Unknown |
| Number of sexual partners: | Opposite sex _____ | Same sex _____ | |
| Dates of hepatitis B vaccine doses: | 1: | 2: | 3: |
| Mother known to be HBsAg positive: | 1- Yes | 2- No | 3- Unknown |

## Comments:

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